Washington State OraQuick® Rapid HIV Testing and Counseling Guide

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Testing and Counseling Guide

This document provides Washington State guidance for the implementation and management of OraQuick® Rapid HIV-1 Antibody testing programs. It is intended as a guide for agencies using, or planning to use, rapid testing for HIV.

This document is consistent with Food and Drug Administration (FDA) rulings regarding the OraQuick Rapid HIV-1 Antibody test as of September 1, 2003; and, with rules adopted by the Washington State Board of Health as of June, 2003.

Use of trade names and commercial sources is for identification only and does not imply endorsement by the Washington State Department of Health.

Credits

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Material in this document was adapted from: 1) the CDC's "Quality Assurance Guidelines for Testing Using the OraQuick® Rapid HIV-1 Antibody Test"; 2) Project Respect protocols; 3) Seattle King County Department of Public Health's Rapid Testing Materials; and, 4) the Michigan Department of Community Health's Rapid Testing Policies and Procedures Materials.

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TABLE OF CONTENTS

INTRODUCTION

This guidance is designed to assist agencies with rapid testing implementation, program development, and quality assurance. The information in this guide will help agencies that are considering implementing rapid testing make informed decisions regarding the appropriateness of this testing technology for their situation.

The OraQuick rapid test has several advantages over the standard HIV antibody test that make this technology worth considering. Rapid HIV testing can:

- Increase the number of persons at high risk for HIV who obtain HIV counseling, testing and referral services.
- Increase the number of persons testing for HIV who learn their test results.
- Increase the early identification of new HIV infections and subsequent referral to care, prevention, and case management services.
- Decrease the need for follow-up activities for clients who do not return for their HIV test results and associated prevention counseling.
- Provide important information useful for post-exposure treatment decisions in occupational exposure, accidental sexual exposure, and childbirth circumstances.

However, even with these advantages, adoption of rapid HIV testing presents Washington State health departments and community based organizations with a number of practical challenges ranging from staff training (to perform the test, document test results, provide preliminary results, and deal with biohazardous materials) to the challenges of maintaining environmental control of the test kit procedure, modifying prevention counseling strategies, and adjusting clinic client flow for this new testing technology. Because of these challenges, agency capacity for staff training, quality assurance of test performance, and maintenance of testing procedures and policies are critical elements to consider before implementation.

In general, rapid testing may be an appropriate technology to consider if a setting or agency has the capacity for staffing, providing internal program quality assurance, maintaining strict control of confidential information and test procedures, controlling the testing and storing of the test kits, conducting confirmatory specimen collection, and, providing effective referrals. However, even with agency capacity, rapid testing may still not be an appropriate technology due to cost factors and the practical challenges of the test.

Agencies with strong capacity may want to consider rapid testing if they serve communities at increased risk for HIV who are not currently availing themselves of HIV Counseling, Testing, and Referral (CTR) services. Rapid testing may be one mechanism for encouraging use of these services. In addition, if low return rates for test results are an agency issue, rapid HIV testing may be a useful tool to improve these rates.

BACKGROUND

The OraQuick Rapid HIV-1 Antibody Test is a rapid HIV point-of-care test (testing and results are available in one visit).

The FDA approved the OraQuick rapid HIV-1 antibody test in November, 2002, and declared the test a "waived" test in February, 2003. This waiver, under the Clinical Laboratory Improvement Amendments (CLIA), allows for OraQuick to be performed relatively easily in a wide variety of non-clinical and outreach settings.

This test uses whole blood gathered from a fingerstick. Results are available within 20 to 60 minutes, although associated procedures related to informed consent and prevention counseling lengthen the time of any session.

This rapid test is a screening test. All positive (preliminary reactive) results must be followed up with a confirmatory test. Negative results do not need additional testing. Agencies implementing rapid testing must assure a system of confirmatory testing for preliminary reactive results (see: CONFIRMATORY SPECIMEN COLLECTION, page 27).

The test has a high level of accuracy at over 99% sensitivity. Although OraQuick is a highly accurate test, as with any screen test, a risk of false positives exists. The likelihood that a positive result from OraQuick is false decreases as the prevalence of HIV within a setting increases (i.e., the more HIV present in the population being tested, the less likely that a given result will be false).

The test is simple and when the manufacturer's directions are followed correctly, it can provide reliable results. However, mistakes can occur at any point in the testing process. Quality assurance and control of the entire testing process are critical to reduce mistakes and increase reliability of results.

THE TEST

(from the OraQuick® Rapid HIV-1 Antibody Test insert)

The OraQuick Rapid HIV 1 antibody test is a single-use, qualitative immunoassay used to detect antibodies to Human Immunodeficiency Virus Type 1 in fingerstick whole blood specimens.

The OraQuick rapid test is comprised of a single-use test device and a single-use vial containing a pre-measured amount of a buffered developer solution. Each component is sealed in a separate compartment of a single pouch for the test. The OraQuick rapid test utilizes a proprietary lateral flow immunoassay procedure. The plastic housing of the device holds an assay test strip comprised of several materials that provide the matrix for the immuno-chromatography of the specimen and the platform for indication of the test results.

The assay test strip, which can be viewed through the test device result window, contains synthetic peptides representing the HIV envelope region and a goat anti-human IgG procedural control immobilized onto a nitrocellulose membrane in the Test (T) zone and the Control (C) zone, respectively.

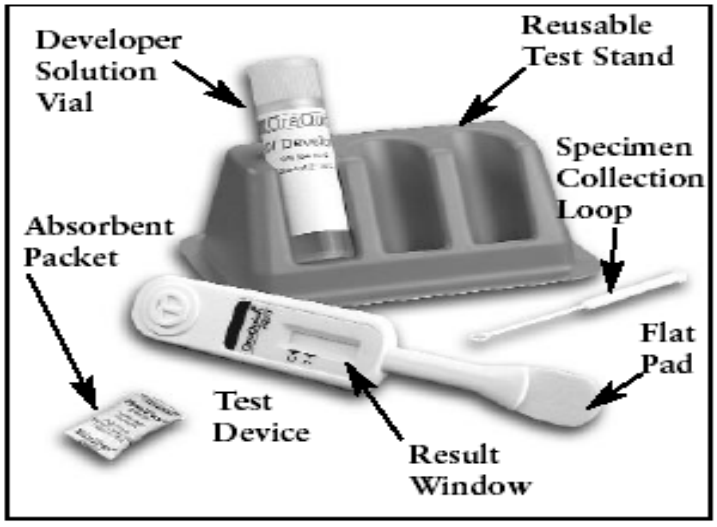
A fingerstick whole blood specimen is collected with a specimen collection loop and transferred into the vial of developer solution, followed by the insertion of the test device. The developer solution facilitates the flow of the specimen into the device and onto the test strip. As the diluted specimen flows through the device, it rehydrates the protein-A gold colorimetric reagent contained in the device. As the specimen continues to migrate up the strip, it encounters the T zone. If the specimen contains antibodies that react with the antigens immobilized on the nitrocellulose membrane, a reddish-purple line will appear, qualitatively indicating the presence of antibodies to HIV-1 in the specimen. The intensity of the line color is not directly proportional to the amount of antibody present in the specimen.

Further up the assay strip, the sample will encounter the C zone. This built-in procedural control serves to demonstrate that a specimen was added to the vial and that the fluid has migrated adequately through the test device. A reddish-purple line will appear in the C zone during the performance of all valid tests, whether or not the sample is positive or negative for antibodies to HIV-1.

The test results are interpreted after 20 minutes but not more than 60 minutes after the introduction of the test device into the developer solution containing the test specimen.

OraQuick Rapid HIV-1 Antibody Test kits include the following:

- a reusable test stand;
- a single-use specimen collection loop;
- a vial containing developer solution; and,
- the test device
- absorbent packet (to absorb moisture within the test kit packet). Not for use during the testing procedure.



LICENSE REQUIREMENTS

Site License Requirements

The Washington State Medical Test Site Law, Chapter 70.42 RCW, requires all sites that perform clinical laboratory testing to obtain a state Medical Test Site (MTS) license.

The OraQuick Rapid HIV 1 Antibody Test has been classified under the Federal Clinical Laboratory Improvement Amendments (CLIA) and the Washington State MTS rules as "waived". This requires all entities conducting rapid HIV testing to obtain a MTS license (Category: Certificate of Waiver). The state MTS license takes the place of a federal CLIA certificate.

If the site already has a MTS license that covers other laboratory testing that is being performed, rapid HIV testing can be performed under that license. However, the site must still inform the Department of Health (at the address below) that this testing will be added to their existing license.

To obtain a license application contact:

Department of Health
Office of Laboratory Quality Assurance
1610 NE 150th St.
Shoreline, WA 98155
(206) 361-2802

or: www.doh.wa.gov/lqa/htm

The fee for a two-year Certificate of Waiver license is $150.00. A fee statement will be sent once the license application has been received. If the site already has a MTS license that covers other laboratory tests, there will not be an additional fee for adding the rapid HIV test.

Testing Personnel License Requirements

The Washington State Health Care Assistants Law, Chapter 18.135 RCW, requires certification of all unlicensed individuals who may be administering skin tests, subcutaneous, intradermal, intramuscular, and intravenous injections, or performing minor invasive procedures to withdraw blood and/or hemodialysis (including finger sticks). Venous and capillary collection of blood specimens are procedures that require certification as a Health Care Assistant for all unlicensed individuals.

To obtain information regarding the Health Care Assistant certification, contact:

Health Professions Quality Assurance
Customer Service Center
PO Box 47865
Olympia, WA 98504

Email: hpqa.csc@doh.wa.gov
Phone: (360) 236-4700
Technical Assistance: (360) 236-4942

NOTE: The Revised Code of Washington 70.24.120 exempts staff employed as public health sexually transmitted disease case investigators from this requirement.

SPECIMEN COLLECTION OVERSIGHT/SUPERVISION

The following three categories of personnel have the authority to collect blood specimens for rapid HIV testing through finger sticks (for the rapid test) and venipuncture (for confirmatory specimen collection):

- some licensed health care professionals (whose scopes of practice allow it);
- certified health care assistants; and,
- sexually transmitted disease case investigators.

However, even as they all have authority to collect blood specimens, they have different requirements for supervision and oversight.

Licensed Health Care Professionals

The scope of practice of some licensed health care professionals (including physicians and nurses) allows those licensed individuals to collect blood specimens by finger stick and venipuncture. For those physicians whose licenses allow for blood specimen collection by finger stick and venipuncture, no additional supervision or oversight is needed. RNs and LPNs do need oversight of at least a written order or protocol from a physician.

Certified Health Care Assistants

Certified health care assistants are individuals who have been certified as health care assistants through the delegation of a licensed health care professional (see bottom of previous page for health care assistance certificate requirement). Certified health care assistants who perform blood specimen collection require blood specimen training and supervision by a licensed health care practitioner.

For the rapid test finger stick, the supervisor need not be physically present, but must be immediately available. "Immediately available" means in immediate contact for consultation by any means, electronic, or otherwise, within a short period of time. Immediate cell phone contact fulfills this requirement.

In addition to having this consultation available, policies and procedures should be in place which direct the health care assistant to call "911" for emergency assistance in the event of an adverse reaction to a finger stick.

To perform a venipuncture, health care assistants must have the supervising practitioner on the premises and immediately available for consultation and assistance during the procedure to withdraw blood (RCW 18.135.020; WAC 246-826-030).

Staffing and supervision policies and procedures for each test site should reflect this.

Sexually Transmitted Disease Case Investigators

Sexually transmitted disease case investigators are individuals who:

1) are employed by public health authorities;
2) have been trained by a physician in proper specimen collection procedure; and,
3) possess a statement signed by the instructing physician that this training has been successfully completed.

Sexually transmitted disease case investigators are authorized to perform both venipuncture and finger sticks for the purpose of specimen collection for sexually transmitted disease tests. They can perform this specimen collection without supervision (RCW 70.24.120).

PERSONNEL

Having qualified, trained staff to perform and supervise OraQuick testing is one of the most important factors for both ensuring accurate, reliable results and quality client services.

Since the OraQuick test is waived under CLIA, there are no specific State or Federal requirements for who can perform the test. (However, there are State requirements for who can collect specimens. See: "Testing Personnel License Requirements", bottom of page 5.)

The following qualities should be considered when selecting personnel:

- ***Sincerity and Commitment***
  A dedication to performing testing according to defined procedures. Testing personnel must be able to precisely follow directions for structured tasks without compromise.

- ***Literacy***
  The ability to read instructions and record results is critical.

- ***Organizational Skills***
  Organizational skills are critical. Managing testing materials and the testing process, as well as documentation of temperatures, the testing process, and testing results, all require an ability to maintain careful and consistent organization. Accuracy of results depends on this skill.

- ***Decision-making Skills***
  Testing personnel should be able to interpret results and be able to recognize and handle problems that might come up.

- ***Communication Skills***
  Verbal communication skills are essential. If the person performing the test also is the one who explains the test, shares results, and/or other information with the person being tested, being able to communicate clearly is critical.

- ***Ability to Maintain Confidentiality***
  Confidentiality must be maintained at all times. Confidentiality with information (both verbal and written, regarding client identity, testing, test results, and risk information) is a critical issue in Counseling and Testing for HIV.

  If the person who is providing testing and counseling is a person who also lives and works within the community served, skills in maintaining confidentiality are absolutely essential. The community served must be able to trust that confidential information will not be disclosed.

- ***Ability to Maintain Professional Boundaries***
  Professional boundaries with clients must be maintained at all times. The ability to maintain professional boundaries becomes especially important if the person who is providing testing and counseling is a person who also lives and works within the community served.

Training is crucial to ensuring quality testing. Staff should be fully trained on how to perform their assigned tasks and responsibilities. Training should be documented for each staff member (see: Appendix A, for an example of a Training Checklist).

The training program should include:

- How to store (and where applicable, transport) test kits and document storage temperatures.
- How to perform the test and controls, including procedures performed before, during, and after testing (including documentation of results and controls).
- Confirmatory specimen collection techniques: blood-draw and/or oral fluid collection.
- Counseling Protocols.
- Confidentiality, Ethics, Washington State Law.
- The use and importance of Universal/Standard precautions and biohazard safety (OSHA/WISHA).

CONFIDENTIALITY

Confidentiality of records, personal information gathered from clients, HIV testing, and test results, is of the utmost importance.

All client information and records must be maintained using an approach consistent with Washington law (RCW 70.02 and RCW 70.24) and, if applicable, the Privacy and Security Requirements promulgated by the federal government in the Health Insurance Portability and Accountability Act (HIPAA). Client information must be kept strictly confidential and records should be managed and stored in a secure manner.

Agencies providing rapid HIV testing must develop confidentiality policies and procedures that will prevent unauthorized persons from learning information shared in confidence. Confidential information includes any material, whether oral or recorded in any form or medium that identifies (or can readily be associated with the identity of) a person and is directly related to their health and care. All information relating to an individual's HIV/AIDS status is protected under medical confidentiality guidelines and legal regulations (RCW 70.24) (WAC 246-100). In recognition of the very sensitive nature of these conditions, medical record protection for HIV and AIDS, like those for substance abuse and mental health, are protected more rigorously than other medical information.

Minimum professional standards for any agency handling confidential information should include providing employees with appropriate information regarding confidentiality guidelines and legal regulations (RCW 70.24, RCW 70.02, and where applicable, the federal HIPAA privacy regulations).

All staff involved in HIV testing and counseling activities with access to testing results and counseling information should sign a confidentiality statement acknowledging the legal requirements under state and federal law not to disclose HIV/AIDS information.

PROGRAM POLICIES AND PROCEDURES

Quality assurance and control of the entire testing process are critical to reduce mistakes and increase reliability of results. The test is simple and when the manufacturer's directions are followed correctly, it can provide reliable results. However, mistakes can occur at any point in the testing process (see Appendix H: Rapid Testing – What Can Go Wrong). Therefore, agencies should develop an overall program policy which at minimum:

1) Identifies the person(s) responsible for managing the Rapid Testing Program.

2) Assures written procedures (step-by-step instructions) are available to all staff involved in testing (see examples of written procedures throughout this guide).

3) Identifies the person(s) who will verify testing process.

4) Ensures staff know how to perform process and procedures.

5) Ensures that appropriate licensing requirements are met (see: Page 5, "Licensing Requirements").

6) Assures logs are established and maintained and identifies the person(s) who will maintain logs.

7) Ensures that Federal biohazard safety rules are met.

Each agency should also develop and follow written policies and procedures for the following program activities:

1. **Training of testing personnel and competency assessment**
   - Documentation of training in all aspects of testing
   - Continued competency assessment documented annually
   - Current Health Care Assistant certification if needed
   - HIV Testing Information and Counseling Skills

2. **Storage of test kits and control materials**
   - Maintain temperature log for storage of test kits
   - Maintain temperature log for storage of controls (refrigerator)
   - Document corrective action as needed
   - Sup Supervisory or director review

3. **Test policies and procedures**
   - Reviewed and approved by supervisor/director
   - Monitored when new testing kits are received for any changes in package insert

4. **Specimen collection/shipping/disposal**
    - Proper labeling of specimens as needed
    - Appropriate packaging for shipping
    - Universal precautions followed
    - Biohazard waste/sharps containers available and appropriately handled for disposal

5. **Performance and reporting of test procedure**
    - Record built-in control results and client results on medical record
    - Fingerstick specimen collection procedure
    - Rapid test kit procedure
    - Venipuncture and/or Orasure specimen collected and sent to reference laboratory for confirmatory testing on preliminary positive test results
    - Maintain temperature log for testing area
    - Supervisory or director review

6. **Testing and review of quality control (QC) samples**
    - Record lot numbers and expiration dates of test kits and QC samples when opened
    - Record results of QC samples and any necessary corrective action
    - HIV Reporting of positive confirmatory test results (confidential tests)
    - Supervisory or director review

7. **Counseling**
    - Appropriate test information to give to clients (window period, WAC requirements, preliminary results, etc.)
    - Informed Consent procedure including Anonymous vs Confidential Testing
    - HIV Prevention Counseling
    - Partner Notification and Referral
    - Care, Case Management, and other Referrals

Additional guidance that should be considered when developing policies and procedures:

1) Washington State HIV/AIDS Counseling and Partner Notification Guide (1996)
2) Washington State Partner Counseling and Referral Services Guide (2001)
3) Revised Guidelines for HIV Counseling, Testing, and Referral (CDC, 1998)
4) Quality Assurance Guidelines for Testing Using OraQuick Rapid Antibody Test (CDC, 2003)

For Washington State guidances, call Claudia Catastini, Washington State Department of Health: 360-236-3422.
For CDC guidances, contact the CDC website: http://www.cdc.gov/hiv/

INTERAGENCY LINKAGES AND AGREEMENTS

Interagency linkages and agreements provide the foundation that assures smooth processes for confirmatory testing and client referral into care and treatment.

Documenting these agreements allows for clear communication between agencies.

Agencies should establish formalized, documented, interagency agreements for confirmatory testing procedures, client referral to case management and care, partner notification services, and HIV prevention services. These agreements should include agency contacts, roles and responsibilities, confidentiality, quality assurance, and grievance procedures.

- **Confirmatory Testing**
  Establish formalized linkages (with appropriate documentation) with a laboratory for confirmatory testing of preliminary positive rapid tests.

- **HIV Care Services**
  Arrange linkages (with appropriate interagency agreements) between the testing program and appropriate medical care for medical follow-up care of persons who have HIV infection.

- **Partner Counseling**
  Arrange formalized linkages (with appropriate policies, procedures, and interagency agreements) in order to assure Partner Counseling and Referral Services (PCRS). The agency providing rapid testing can elicit partners or can actively refer HIV infected clients to the local health jurisdiction for partner elicitation counseling. However, the recommendation is that the local health jurisdiction provides field investigation and notification of partners.

- **HIV Prevention Services**
  Arrange formalized linkages (with appropriate policies, procedures, and interagency agreements for referrals) to programs for HIV prevention services for high-risk negative individuals and programs serving HIV infected clients.

PRIOR TO PROGRAM IMPLEMENTATION

Even though the test is simple to use, things can go wrong (see Appendix H: Rapid Testing – What Can Go Wrong). There are a number of activities and techniques that are necessary to ensure that the testing procedures are performed correctly, the environment is suitable, and the test kit works as expected to produce accurate and reliable results.

To achieve minimum standards of test quality control, and help find and prevent testing problems, the following should be completed before testing begins:

1) staff should be trained in the test process (See: Appendix A), and
2) policies for testing, counseling, and documentation procedures should be in place.

Before offering the test to clients, each site should verify that the testing process works as planned.

VERIFICATION SHOULD BE COMPLETED BEFORE TESTING IS OFFERED.

Verification includes ensuring that:

- staff have been trained and are able (competent) to perform their assigned tasks,
- the test kits work as expected (e.g., make sure the test gives accurate results for a referenced panel of non-reactive, weakly reactive, and reactive specimens),
- logistics for providing confirmatory testing are in place and function effectively, and
- biohazardous waste handling is in place.

IMPLEMENTATION SEQUENCE

- Determine if agency has capacity to implement rapid testing
- Determine if rapid testing is right for proposed clients
- Determine if rapid testing is right for the proposed venue
- Get site license
- Set-up monitoring systems
    - specimen tracking
    - device tracking
    - processing logs
    - refrigeration logs
    - ambient temperature logs, etc.
- Set-up records systems
    - client charts
    - consent forms
    - results logs
- Set-up materials procurement, tracking, monitoring
    - Test Kits and Control Kits
    - confirmatory specimen collection, labeling, and shipping
    - biohazardous waste storage
- Set-up material storage
    - dedicated refrigerator for controls *(No lunches allowed!)*
    - kits and other materials
- Set-up biohazardous waste management and disposal system
- Set up bloodborne exposure management plan
- Set-up procedure for confirmatory testing and develop formalized relationship with a laboratory with appropriate documentation
- Set-up specimen transport system
- Set-up partner notification and referral system
- Set-up linkages and interagency agreements for appropriate medical and social referrals for comprehensive follow-up care of persons who have HIV infection.
- Identify & train appropriate staff
    - Test Kit technique
    - Finger-stick; Confirmatory specimen collection
    - Counseling
- Set-up staff QA & supervision.
- Verify Rapid Testing Program is ready for implementation
    - Staff are trained and competent
    - Test kits work
    - Policies and procedures are in place and function effectively
    - Logistics for confirmatory testing are in place and function effectively
    - Biohazardous waste handling is in place

AGENCY CONSIDERATIONS -- WORKING TOOLS

Because implementation of rapid testing presents significant challenges, agencies should carefully consider whether or not this technology is appropriate for their agency, their clients, and, the venues in which they propose to use OraQuick.

When considering whether or not to implement rapid testing, agencies should ask the following questions:

1) Agency Capacity: **Does our agency have the capacity to provide rapid testing?**
2) Client Appropriateness: **Is rapid testing appropriate for the clients we plan to serve?**
3) Venue: **Is rapid testing appropriate for the venue we plan to use?**

This section provides tools to assist agencies in answering the above questions.

Does our agency have the capacity to provide rapid testing?

The following tool is designed to help agencies assess their capacity to provide rapid testing. The table is split into three columns. The first column (on the left) lists elements that are critical to the implementation of rapid testing. The center column (labeled "Page #") contains the page number of this document that explains the element. The third (empty column) on the right is for agencies to fill out with either a "Yes" or a "No".

Use a "Yes" if your agency has the capacity to accomplish the element as described on the referenced page in this document. Use a "No" if your agency does not have the ability to accomplish the element.

Each of the following agency capacity elements is critical and necessary to successful implementation of rapid testing.

Therefore, an agency should only consider implementing rapid testing if they can fill out this table with a "Yes" for all of the following elements:

Element	Document Page #	Capacity ? Yes/No
Licenses		
1. Washington State Medical Test Site License (Category: Certificate of Waiver).	5	
2. Health Care Professional Licenses, Health Care Assistant Certifications, and/or, designation of Sexually Transmitted Disease Case Investigators for Public Health staff collecting blood specimens through finger stick and venipuncture.	6	
Program Policies and Procedures in Place		
3. Training of Testing and Counseling Personnel	Appendix A	
4. Storage of Test Kits	21	

5. Maintenance and Timing of Controls	22	
6. Maintenance and Documentation of Temperature	23	
7. Fingerstick Procedure	26	
8. Test Kit and External Control Kit Procedures	27	
9. Confirmatory Specimen Collection	30	
10. Test Clean Up and Lab Safety Procedures	31	
11. Policy and Procedures for shipping specimens that meet biohazardous material shipping and handling requirements	30	
12. Biohazardous Waste Management System and Procedure	OSHA/WISHA	
13. Test Result Documentation Procedure	32	
14. Bloodborne Pathogens Exposure Plan	Appendix I	
15. Partner Notification and Referral Services Plan	46	
16. Referral to Care Services; Case Management; and other appropriate referrals	45	
17. Reporting of HIV cases (after confidential Confirmatory Positive test result)	34	
18. Comprehensive program Quality Control	10, 11	
Medical Records		
18. Established Medical Records System (that meets state & federal confidentiality requirements) with Medical Records and Associated protocols	N/A	
19. Consent form	Appendix M	
Trained Staff		
20. Staff trained to conduct Rapid Test Kit; Rapid Test Controls; Finger Stick	Appendix A	
21. Staff trained to conduct Confirmatory Specimen Collection, Testing Documentation; and, Shipping	Appendix A	
22. Staff trained to document Temperatures; Testing (Kits and Controls); and, Results	Appendix A	
Staff with Appropriate Interest and Capacities for Rapid Testing		
23. Staff who have received training in HIV Counseling and who are willing and able to provide test results to clients using the single-session model	Appendix A	
24. Staff who are familiar with the WAC requirements for counseling & testing	Appendix A	
25. Staff who are willing and able to counsel with the additional counseling challenge of providing preliminary positive results	Appendix A	
26. Staff who are willing and able to perform fingersticks, run the Rapid Test Kits, collect confirmatory specimens, and handle biohazardous waste	Appendix A	

27. Staff who are willing and able to monitor the environment and run controls	Appendix A	
28. Staff who are willing and able to accomplish the significant record-keeping and documentation requirements	Appendix A	
Supervision Capacity		
29. For those programs that will utilize Certified Healthcare Assistants, licensed health care practitioner supervision **on site** for venipuncture blood specimen collection ***and*** **in immediate contact** for finger stick blood specimen collection.	6	
30. A clear supervisory structure (with delineated roles and responsibilities) to ensure responsibility for training and guidance, oversight of testing procedures, and coordination of program.	All	
31. A supervisory structure with skills and capacities to assure quality control.	All	
Coordination; Collaboration; and Linkages		
32. Establish formalized linkages (with appropriate documentation) with a laboratory for confirmatory testing of preliminary positive rapid tests	12	
33. Arranged linkages (with appropriate interagency agreements) between testing program and appropriate medical care for medical follow-up care of persons who have HIV infection.	12	
34. Formalized linkages (with appropriate policies, procedures, and interagency agreements) in order to assure PCRS	12	
35. Formalized linkages (with appropriate policies, procedures, and interagency agreements for referrals) with high-risk negative interventions and interventions for HIV infected clients.	12	
Environment		
35. Refrigeration for Storing Controls.	21	
36. Controlled Environment for storing kits within temperature parameters.	21	
37. Controlled Environment for transporting kits (if outreach testing).	35	
Miscellaneous		
38. The cost of the controls is in alignment with the agency expenditure plan for testing.	N/A	
39. Capacity and system to purchase and/or obtain test kits.	N/A	
40. Capacity and system to purchase all supporting materials (fingerstick, confirmatory specimen collection and shipping, biohazardous waste storage and transport, etc).	21	
41. Capacity to transport records confidentially.	35	

Is rapid testing appropriate for the clients we propose to serve?

The following tool offers questions that can guide an agency in assessing whether or not rapid testing is appropriate for the clients they plan to serve.

The five elements in this chart are not critical and necessary for the successful implementation of rapid testing. However, in terms of serving client needs, they suggest where it would be most appropriate to implement.

Therefore, while an agency could choose to implement rapid testing even if its answers are all "No" for this chart, agencies should **only consider implementing rapid testing if they have at least one "Yes" on this chart.**

Element	Yes or No
1. *Client population has substantial non-return rates for HIV test results, especially if non-return rate is high for clients who test positive.*	
2. *The conventional 1- to 2-week waiting period for results is a barrier to testing for a substantial number of clients.*	
3. *Conventional venipuncture is a barrier to testing for clients*	
4. *In clinics where blood specimen collection for STDs (including HIV) is in place, clients would prefer to have an additional fingerstick in order to receive HIV results quickly.*	
5. *Client population requests rapid testing.*	

Is rapid testing appropriate for the proposed venue?

The following tool offers questions that can guide an agency in assessing whether or not rapid testing is appropriate for use in a planned venue.

The last two *italicized* elements in this chart are not critical and necessary for the successful implementation of Rapid Testing. Therefore, an agency could choose to implement rapid testing even if it answers "No" to these last two elements (13 and 14).

However, elements 1-12 are critical and necessary for the successful implementation of rapid testing.

Agencies should only implement rapid testing in a site where they are able to fulfill each of the elements numbered 1 through 12.

Element	Yes/No
1. There is an ability to maintain confidentiality of client services and patient records.	
2. The site has the capacity to handle client flow and potential increase in client demand.	
3. The site has a place for clients to wait and/or sign up prior to testing, and, when applicable, there is a place for clients to wait to receive results.	
4. There is enough private space for testing and counseling.	
5. There is an ability to maintain stable temperatures (between 59 & 80 degrees).	
6. The site has appropriate level of qualified, trained, staffing.	
7. There is adequate lighting and there are adequate flat surfaces for both running and reading the test kits.	
8. The venue is appropriate context for providing preliminary positive results.	
9. Confirmatory specimen collection, transport, and storage system works at this site.	
10. A Biohazardous waste collection, storage, and transport system works at this site.	
11. The site conforms to OSHA/WISHA standards and has the capacity to handle bloodborne pathogens occupational exposures	
12. Members of the priority population remain at the venue long enough to receive counseling, testing, and results.	
13. *The venue serves a high-prevalence population (≥ 1%).*	
14. *There is evidence of substantial under-screening of a high prevalence population.*	

RAPID TESTING PROCEDURES

TEST KIT STORAGE

Materials

Check inventory of test kits and materials on an appropriate schedule (e.g. at the first of each month). Assure that appropriate numbers of test kits, control kits, and necessary associated test materials are available. Maintain a log of materials.

- OraQuick Rapid HIV-1 Antibody Test kit (includes specimen collection loop)
- OraQuick Rapid HIV-1 Antibody Test kit Controls
- Timer or watch capable of timing 20 to 60 minutes
- Antiseptic wipes
- Sterile lancets
- Sterile gauze pads
- Latex, vinyl or nitrile disposable gloves
- Clean, disposable, absorbent workspace cover
- Biohazard waste containers
- Bandages
- Ammonia pellets
- 10% bleach solution and paper towels for wiping up spills

Storage of Kits and Controls

Store unused OraQuick Rapid HIV-1 Antibody Tests **unopened** at 2°C to 27°C (35°F to 80°F). Do not open the Divided pouch until ready to perform a test.

NOTE: If stored refrigerated, ensure that the Divided pouch is brought to **room temperature** 15°C to 27°C (59°F to 80°F) before use.

Store External Controls in a refrigerator at 2°C to 8°C (35°F to 46°F). Open the kit control vials only when performing the tests. Recap and store the vials in their original container after use. Dispose of unused portions of opened vials after 21 days.

Shelf Life

Do not use the test or controls beyond the expiration date printed on the divided pouch or on the controls.

CONTROLS

Built In Controls

Each test kit has a built-in control that demonstrates the validity of the assay. A reddish purple line in the control ("C") area of the Result Window indicates that a specimen was added and that the fluid migrated appropriately through the Test Device. The control line will appear on all valid tests, whether or not the sample is Reactive or Non-Reactive. Built-in control results should be recorded on the test result log.

External Controls

In addition to the internal control on each test kit, there are external controls that need to be performed. The external quality controls are both a positive and a negative control (human plasma based reagents) and are usually purchased separately from the actual test kits.

The positive and negative external test controls are used to verify the ability of the person to properly perform the test and interpret the result.

You **MUST** run these controls when:

- New testing personnel perform the test.
- Opening a new test kit lot.
- A new shipment of test kits is received.
- The temperature of the test kit storage area falls outside of 2°C to 27°C (35°F to 80°F).
- The temperature of the testing area falls outside of 15°C to 27°C (59°F to 80°F).
- At periodic intervals (e.g., new location, lighting, temperature, etc.) as determined by the Test Site director.

Protocol to test the controls is the same as the specimen testing protocol except the negative or positive control (reagents) samples are used, not a blood specimen.

Do not use the controls past the expiration date printed on the outer carton. Open kit control vials only when you are performing tests. Recap and store the vials in their original container. Opened vials expire 21 days after they are put in use. Do not use controls if the reagent appears visually cloudy or discolored.

The positive control will produce a reactive test result and has been manufactured to produce a very faint Test ("T") line. The negative control will produce a non-reactive test result.

Record results on the external control log sheet each time these controls are run.

Document the control results and any corrective action taken when the results are not as expected. Maintain an External Control Log (see: Appendix D) to document performance of external positive and negative control tests. The director or supervisor should review the External Control Log on a monthly basis.

If the positive and negative control results are incorrect, open a new control vial and repeat. If the results are still unacceptable, do not perform client testing using that lot number of test kits. Contact OraSure Technologies Customer Service (800-672-7873) for assistance.

TEMPERATURE DOCUMENTATION

Accuracy of the test kits is dependent on storing and running the tests within specific temperatures (see: “Test Kit Storage”, page 21). Documenting storage temperatures (both refrigerator temperatures for control kits and ambient temperatures for test kits) and ambient testing temperatures is critical to assure accurate and reliable results.

Refrigerator Temperature Log

The purpose of the Refrigerator Temperature Log is to document the temperature of the refrigerator used to store the external controls and other specimens. Refrigerator Temperature Log must be maintained. (See: Appendix B, for Refrigerator Temperature Log.)

- Check and document refrigerator temperature each day.
- Maintain refrigerator temperature at 2°C to 8°C (35°F to 46°F).
- If the refrigerator temperature is 1° to 2° outside of the acceptable range, adjust the refrigerator control accordingly and check the temperature again after one hour.
- If the refrigerator temperature is more than 2° outside of the acceptable range, discard the control specimens, and document under “Corrective Action”.
- The supervisor or director should review and sign the refrigerator temperature logs on a monthly basis.

Ambient Temperature Log

The purpose of the Ambient Temperature Log is to document the temperature of the room where testing is performed. The Ambient Temperature Log must be maintained. (See: Appendix C, for Ambient Temperature Log.)

Note: if test kits are not stored in the refrigerator, an ambient temperature log should also be completed for the kit storage area.

- Check and document ambient temperature each day. If there is a significant change in ambient temperature, re-check temperature and document in log.
- The ambient temperature should be maintained at 15°C to 27°C (59°F to 80°F).
- If the ambient temperature is 1° - 2° outside of the acceptable range, run the external controls and document the results on the external control log. Document the action taken on the temperature control log. Check the temperature again in one hour.
- If the temperature is more than 2° outside of the acceptable range, discontinue testing until the ambient temperature falls within the acceptable range.
- The supervisor or director should review and sign the ambient temperature logs on a monthly basis.

TEST PRECAUTIONS AND LIMITATIONS

Even though the OraQuick test is simple to use, things can go wrong. Follow test precautions and procedures carefully.

Read the package insert completely before using the test kit. Follow the instructions carefully when performing testing. Failure to do so may result in inaccurate test results.

Always have a package insert available for personnel that are performing the test.

Before performing testing, all testing personnel MUST have completed OSHA/WISHA blood-borne pathogens training.

Do not drink, eat or smoke in areas where testing is being performed.

Precautions

- Use all specimen collection loops, test devices, and developer solution vials once and dispose of properly. Do not reuse any of these test components.
- Do not interchange test devices and developer solution vials from kits with different lot numbers.
- Avoid microbial contamination and exercise care in handling the kit components.
- To ensure accurate results, the test device must be inserted into the developer solution vial within 60 minutes after introducing the blood specimen.
- Check to see if an absorbent packet is present inside the pouch with the test device. If the packet is not present when you open it, discard the pouch and test device and use a new one.
- Adequate lighting is required to read a test result.

Limitation of the Test

- The OraQuick test must be used in accordance with the instructions in the package insert to obtain an accurate result.
- Reading test result before 20 minutes or after 60 minutes may yield erroneous results.
- Only fingerstick blood must be used.
- This test is intended as an aid in the diagnosis of infection with HIV-1.
- For a reactive result, the intensity of the test line does not necessarily correlate with the concentration of antibody in the specimen.
- A non-reactive result does not preclude the possibility of exposure to HIV or infection with HIV. An antibody response to recent exposure may take several months to reach detectable levels.

Contra-indications

- It is not recommended to run this test when the ambient temperature is greater than 80°. If testing will be conducted in temperatures above 80°, contact OraSure Technologies Customer Service (800-672-7873) for further assistance and guidance.
- No clinical data are available to demonstrate the performance of this test for persons under the age of 13. Therefore, at this time, **it is not recommended to use OraQuick on persons under the age of 13.**

TESTING SET-UP PROCEDURE

1) Stock supplies for charts
    - Registration Forms
    - HIV Test Consent Forms
    - Encounter Forms (if applicable)
    - Chart jackets (if applicable)
    - Purple “Scannable” Bubble Forms (for state-subsidized kits)
    - HIPAA handouts
    - Release of Information Forms

2) Stock handouts/materials for clients
    - Follow-up appointment cards
    - Brochures/Hand-outs
    - Referral sheets
    - Packets of materials for persons with reactive HIV results
    - Condoms, Safe-sex Kits

3) Stock OraQuick Rapid HIV-1 Antibody Tests and Control Kits

4) Check the temperature of the refrigerator used to store controls and other specimens. Use the Refrigerator Temperature Log (see: Appendix B) to document this activity.

5) Check the temperature of the room where testing will be conducted. Use the Ambient temperature Log (see: Appendix C) to document this activity.

6) Perform external controls as indicated by the Quality Control section of the OraQuick Testing Protocol. Document this activity using the External Control Log (see: Appendix D).

7) Stock medical supplies; arrange on desk.
    - OraQuick Rapid HIV-1 Antibody Test kits
    - Sterile lancet
    - Timer or watch capable of timing 20 to 60 minutes
    - Antiseptic wipe
    - Sterile gauze pads
    - Bandages
    - Clean, disposable, absorbent workspace cover
    - Ammonia pellets
    - Latex, vinyl, or nitrile disposable gloves
    - Biohazard bags and sharps container
    - Confirmatory testing supplies
        - venipuncture equipment for specimen collection
        - laboratory requisition for specimen
        - proper shipping containers

8) Stock cleanup supplies
    - 10% Bleach Solution
    - Paper Towels

9) Stock OSHA/WISHA Standard Protective Gear
    - Lab Coat; Protective Eyewear; Gloves

FINGER STICK PROCEDURE

Blood Collection by Skin Puncture for Adult Patients

At all times, use OSHA/WISHA standards for handling biohazardous materials.

Materials and Equipment:

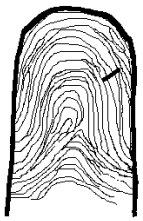
A. Disposable latex gloves (or non-latex if employee and/or patient has a latex allergy).
B. Isopropyl alcohol
C. Cotton balls or gauze
D. Blood lancets for skin puncture
E. Biohazard waste collection and sharps containers
F. Band Aids (optional)
G. Specimen collection loop from Rapid Test kit for micro sampling
H. Disinfectant (10% household bleach) for bench tops

Safety:

A. Use universal precautions as outlined in the Bloodborne Pathogen Plan.
B. Place sharps container close to the collection site.
C. Wear disposable gloves at all times during the procedure.
D. Change gloves between patients.

Procedure:

A. The procedure should be explained to the patient.
B. Select the third or fourth (middle or ring) finger to obtain a sample. Choose a site that is on the side of the fingertip, midway between the edge and midpoint of the fingertip. Thoroughly wash hands with warm soapy water.



C. Warm the finger using friction, warm water, and/or a heating pad.
D. Thoroughly cleanse the chosen site with 70% alcohol. Wipe excess alcohol with sterile gauze. Allow the skin to air-dry. Wet alcohol remaining on the skin will sting the client and may dilute the sample.
E. Hold the finger firmly with one hand, and place the lancet on the pad of the finger (slightly to the side of the center of the finger pad and perpendicular to the fingerprint.
F. Use a sterile, OSHA approved, blood lancet to make a deep puncture (1.5 mm) at the chosen site. (A deep puncture is no more painful that a superficial one, gives a much better flow, and makes it unnecessary to repeat the procedure.) Immediately dispose of contaminated lancet into a sharps container.
G. Using a dry gauze, wipe away the first drop of blood, making certain the area is completely dry.
H. Apply moderate pressure, approximately 1 cm behind the site of the puncture to obtain a drop of blood. Do not 'milk' the finger!
I. Release this pressure immediately to allow re-circulation of the blood.
   - *Touch the specimen collection loop to the drop of blood formed on the surface of the skin.*
   - *Assure that the collection loop is completely filled with blood.*
   - *Insert the collection loop into the test kit vial and stir.*
J. Meanwhile, apply a piece of gauze, (or cotton ball), to the puncture site, using slight pressure until the bleeding has stopped; use a Band-Aid to keep the site clean.
K. Dispose of any contaminated materials in a Biohazard bag or the sharps container.

TEST PROCEDURE*

1. Set up Testing Workspace:
   - Give the Subject Information Pamphlet provided in the kit to the client being tested.
   - Gather the material you need.
   - Allow the test kit to come to room temperature 15°-27°C (59°–80°F) before use.
   - Cover your workspace with clean, disposable, absorbent workspace cover.
   - Set an OraQuick reusable test stand (stand) on your workspace cover. Use only the stand provided.
   - Put on disposable gloves.

2. Open the two chambers of the OraQuick Divided Pouch (pouch) by tearing at notches on the top of each side of the pouch. To prevent contamination, leave the Test Device (device) in the pouch until ready to be used.

3. Remove the developer solution vial from the pouch. Hold the vial firmly in your hand. Carefully remove the cap from the vial by gently rocking the cap back and forth while pulling it off. Set the cap on the workspace cover.

4. Slide the vial into the top of one of the slots in the stand. **DO NOT** force the vial into the stand from the front of the slot as splashing may occur. Make sure the vial is pushed all the way to the bottom of the slot in the stand.

5. Using an antiseptic wipe, clean the finger of the person being tested. Allow the finger to dry thoroughly or wipe with sterile gauze pad. Using a sterile lancet, puncture the skin just off center of the finger pad. Hold the finger downward. Apply gentle pressure beside the point of the puncture. Avoid squeezing the finger to bleed. Wipe away this first drop of blood with a sterile gauze pad. Allow a new drop of blood to form.

6. Pick up an unused collection loop (loop) by the thick handle end. Put the rounded end of the loop on the drop of blood. Ensure that the loop is completely filled with blood. ***Note**: If the loop is dropped or comes in contact with any other surface, discard it in a biohazard waste container. Get a new loop for the collection of the blood specimen*.

7. Immediately insert the blood-filled end of the loop all the way into the vial. Use the loop to stir the blood specimen in the developer solution. Remove the used loop from the solution. Discard the used loop in a biohazard waste container.

8. Check solution to make sure that it appears pink. This means that the blood was correctly mixed into the solution. *If the solution is not pink, discard all test materials in a biohazard waste container. Start the test over using new pouch and collecting a new blood specimen*.

9. Remove the test device from the pouch. **DO NOT** touch the flat pad. *Check to ensure that an absorbent packet is included with the device. If no absorbent packet is present, discard the device and obtain a new pouch for testing*. Label the test device with identifying number or name of the individual being tested. This is especially important if more than one test will be in the test stand at the same time.

10. Insert the flat part of the device all the way into the vial containing blood specimen. Ensure that the flat pad touches the bottom part of the vial. ***DO NOT** cover the two holes in the back of the device with labels or other materials. Doing so may cause an invalid result.*

11. Start timing the test. **DO NOT** remove the device from the vial while the test is running. Pink fluid will appear and travel up the result window. The pink fluid will gradually disappear as the test develops. Read the results **after 20 minutes** but **not more than 60 minutes** in **fully lighted** area.

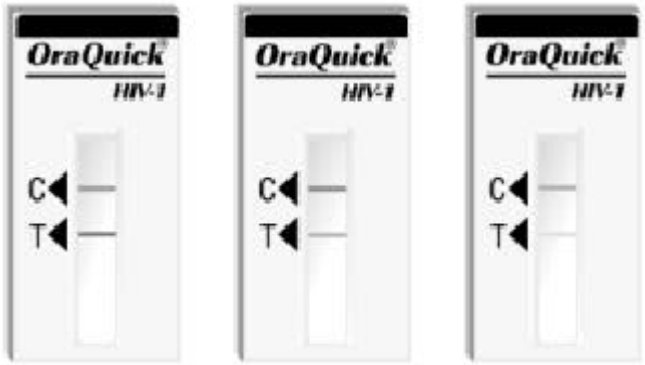
* See: Appendix G, for a flowchart visual of test procedure.

READING RESULTS

A reddish-purple line in the Control ("C") area of the result window indicates that a specimen was added and that fluid migrated appropriately through the test device. The control line appears in both non-reactive and reactive results. *There must be a reddish-purple line in the Control ("C") area for the test to be valid.*

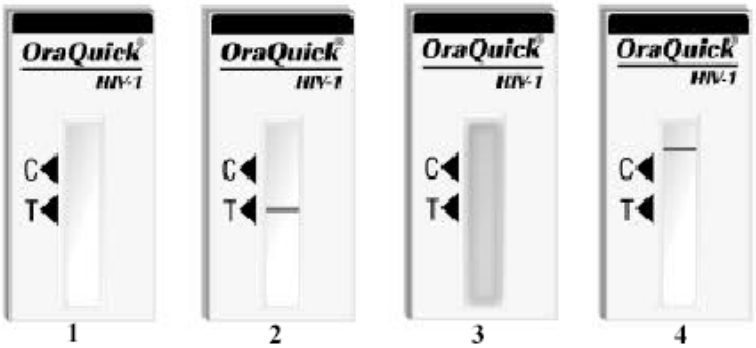
Non-Reactive – A reddish-purple line appears next to the triangle labeled **"C"** and **NO** line appears next to the triangle labeled **"T".** (see example below)

Reactive – A reddish-purple line appears next to both triangles **"C"** and **"T"**. One of these lines may be darker than the other. (see all three examples below)



Invalid Test Results (see below)

- **No** reddish-purple line appears next to the triangle labeled "C" (1 and 2 below), or
- A red background makes it difficult to read the result after 20 minutes (3 below), or
- If ANY of the lines are **NOT** inside the "C" or "T" triangle areas (4 below).



INTERPRETATION OF RESULTS

Invalid Results
If the test result is invalid, a new test must be conducted.

Conduct a new test with a new pouch and a new fingerstick blood sample.

If you are unable to get valid result on an additional test, contact OraSure Technologies Customer Service: **800-672-7873**.

Non-Reactive
A non-reactive test result means that HIV-1 antibodies were not detected in the specimen. The test result is interpreted as **negative for HIV-1 antibodies**.

Almost all individuals with a non-reactive result are **not infected** with HIV. The exceptions are those who have had a recent (within 3 months) exposure to HIV. An exposure within the past 3 months, may, or may not have been cleared up by this test. Therefore, for clients with a recent exposure, retesting should be recommended at a full 3 months from last possible exposure to make sure the client has the most accurate results.

Preliminary Reactive
A reactive test result means that HIV-1 antibodies have been detected in the specimen. The test result is interpreted as **PRELIMINARY POSITIVE for HIV-1 antibodies**.

Further testing is always required to confirm a reactive screening test result. It is essential to explain:

- The meaning of reactive screening test result in simple terms, avoiding technical jargon.
- Emphasize the importance of confirmatory testing and schedule a return visit for confirmatory test results.
- Underscore the importance of taking precautions to prevent transmitting infection to others while awaiting results of confirmatory testing.

<u>All reactive (preliminary positive) test results must be confirmed.</u>

TEST RESULT DOCUMENTATION

Test results must be documented carefully on a test result log (see: APPENDIX E, for an example of a Test Result Log). Because timing is critical for reading results (as results are accurate only during the time period of 20 minutes to 60 minutes after the test is started) the time the result is read should also be recorded.

Staff should be trained in the documentation of results. Before recording results without direct supervision, staff should be observed correctly reading and documenting results.

Careful documentation of the test process and the results (including the results for both the internal and external controls) will allow for quality assurance; insuring accuracy of results while minimizing errors; and, tracking results. Tracking results is important to assure that the correct test result is given to each client.

Documentation of the test process (see Appendix E: Test Result Documentation) should include the following:

- Client ID and Test Date
- Kit Lot # and Expiration Date
- Actual Test “Start” and “End” Times
- Test Result
- The Time the Result is Given to the Client
- The Tester or Counselor Initials
- Internal Control Results
- Confirmatory Testing
    - Tracking #
    - Specimen Type (oral or blood)
    - Result
    - Date Received
    - Date Given to Client

Test process documentation should also include:

- External Controls (see Appendix D: External Control Documentation)

Errors: Errors made by entering incorrect information or placing information in the wrong blank should be corrected by drawing a single line through the mistake(s) and initialing the line in the margin. Do not scribble over errors or use whiteout to cover them up - inspectors and lawyers assume that you are trying to hide something.

CONFIRMATORY SPECIMEN COLLECTION
When the rapid test is reactive, a confirmatory test is required.

1) Collect specimen (either through blood draw or oral fluid collection).

2) Follow appropriate OSHA/WISHA biohazard precautions and clean-up.

3) Label specimen with client code.

4) Package specimen for shipment. For assistance in determining proper packaging, contact the laboratory where specimens are being sent.
Package specimens for shipment in accordance with:

- US Department of Transportation (DOT) Hazardous Materials (HazMat) Regulations 49 CFR Parts 171-180;
- US Postal Service Hazardous Materials Regulations, 39 CFR Part 111;
- International Air Transport Association (IATA) Dangerous Goods Regulations.

5) Fill out Lab Requisition.

- Indicate Reactive Rapid Test
- *Both* EIA and Western Blot (or IFA) should be run. Regardless of EIA results, the specimen *must* proceed to Western blot (or IFA). **Indicate this on lab requisition.**

6) Document on Specimen Transfer Log (see: APPENDIX F, for example of Confirmatory Specimen Transfer Log).

7) When results arrive, document results on test result log (see: APPENDIX E, for example of Test Result Log).

8) If the confirmatory test is **negative**, specimen mix-up must be ruled out versus false preliminary positive result.

- For blood specimens, a confirmatory test should be repeated with a new blood specimen to rule out specimen mix-up.
- For oral fluid specimens, a repeat confirmatory test with a blood specimen should be done.

9) If confirmatory results are **indeterminate**:

- For blood specimens, advise client to return for repeat testing in a month.
- For oral fluid specimens, repeat confirmatory Western blot (or IFA) using a blood specimen.

10) If confirmatory results are **positive**, no further confirmatory testing is recommended.

CLEAN UP PROCEDURES

At all times, use OSHA/WISHA standards for handling biohazardous materials.

1. Used lancets and needles must be disposed of in a sharps container.
2. Dispose of the used test kit materials or specimen collection materials and any other biohazard waste (specimen loop, reaction fluid, test device, gloves, gauze, etc) in a biohazard waste container.
3. Change your gloves between each test or specimen collection to prevent contamination. Throw away the used gloves in a biohazard container.
4. Use a freshly prepared 10% solution of bleach to clean up any spills.
5. Label and package specimens for confirmatory testing.
6. Return supplies to proper storage locations.

SAFETY PROCEDURE

At all times, use OSHA/WISHA standards for handling biohazardous materials.

- Handle specimens and materials contacting specimens as if capable of transmitting infectious agents.
- Do not drink, eat, or smoke in areas where specimens are being handled.
- Cover your workspace with a clean, disposable, absorbent workspace cover.
- Personal protective equipment must be worn when there is a potential for exposure to bloodborne pathogens. Therefore, staff must wear adequate protective gear when collecting and handling fingerstick and venipuncture blood specimens. At minimum, wear gloves when performing fingersticks. Wash hands (or sanitize with disinfectant hand wipes or fluid) thoroughly after collecting each specimen.
- Dispose of gloves in a biohazard waste container after use.
- Dispose of all test specimens and materials used in the test procedure in a biohazard waste container.
- Lancets should be placed in a puncture-resistant container prior to disposal.
- The recommended method of disposal of biohazard waste is autoclaving for a minimum of 1 hour at 121ºC. Disposable materials may be incinerated. If not providing autoclaving, an agency must establish biohazardous waste pickup and disposal services with an appropriate contractor. Contact the local health department for direction on waste disposal.
- Liquid wastes may be mixed with appropriate chemical disinfectants. A solution of 10% bleach (0.5% solution of sodium hypochlorite) is recommended. Allow 60 minutes for effective decontamination.
- **NOTE: Do not autoclave solutions that contain bleach.** For additional information on biosafety, refer to CDC's 1988 MMWR "Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Blood-borne Pathogens in Health-Care Settings".*
- Wipe all spills thoroughly with a solution of 10% bleach or other appropriate disinfectant.

HIV REPORTING

In Washington State, AIDS has been reported since 1983, symptomatic HIV infection since 1987, and asymptomatic HIV infection since 1999.

Agencies providing confidential HIV testing should develop policies and procedures (including roles and responsibilities) in order to assure the timely reporting of HIV cases to the Local Health Department.

Note: Positive HIV results obtained through anonymous testing are not reportable. Therefore, if an agency provides **only** anonymous testing, reporting is not required.

However, it is recommended that agencies offer and encourage confidential confirmatory testing in order to assure that clients receive confirmatory results, PCRS services, and referral into appropriate case management and care services.

State laws and health department security and confidentiality rules protect the identity of persons reported with HIV or AIDS. Anyone who violates these confidentiality laws may be found guilty of a gross misdemeanor and may be subject to action for reckless or intentional disclosure up to a fine of $10,000 or actual damages, whichever is greater (RCW 70.24.080, RCW9A.20.021, RCW70.24.084)

Case report information for individual patients is NEVER shared with anyone. Case reports are kept in locked rooms with access limited to authorized personnel who are trained in maintaining the confidentiality and security of these records.

For the address of the local health department in your county, assistance in developing a reporting policy, or information on HIV/AIDS reporting, call the state office:

Olympia: (360) 236-3418 or (360) 236-3419
Kent: (253) 395-6731 or (253) 395-6732.
Toll free number: (888) 367-5555.

SPECIAL CONSIDERATIONS FOR RAPID TESTING

Off-site Testing

Transportation of Test Kits and External Controls

Test kits and controls should be transported in coolers with ice. Temperature of the cooler should be documented.

- Because external controls must be maintained at 2°C to 8°C (35°F to 46°F), they must be transported in a cooler.
- Test kits should be transported inside the cooler in order to assure that they are transported within their required temperature range: 2°C to 27°C (35°F to 80°F).

Temperature

When considering implementation of rapid testing in mobile test clinics, be sure that the site location will be able to control ambient temperatures. The location must be able to maintain temperatures between 15°C to 27°C (59°F to 80°F).

Lighting

The site must also have consistent, adequate lighting for reading the test kit results.

Surface Area

A flat surface will be necessary for placement of the test kit.

OSHA/WISHA Standards

The site where the specimen collection is conducted must have the capacity to meet OSHA/WISHA standards for bloodborne pathogens, including readily accessible hand-washing facilities. If hand washing facilities are not feasible, antiseptic towelettes or antiseptic hand-rubbing and washing products must be provided. Staff must also wear adequate protective gear when collecting and handling fingerstick and venipuncture blood specimens.

Documentation

Because documentation of temperature, controls, test kit timing, and results is critical, assure that all forms for documentation are part of the off-site system.

RAPID TESTING
COUNSELING PROCEDURES

HIV COUNSELING WITH RAPID TESTS

HIV counseling encompasses three components:

1) providing information;
2) assuring informed consent; and,
3) prevention counseling.

As of July 2003, Washington State law requires that all three of these components are included when providing an HIV test (WAC 246-100-209). The basic information about HIV and HIV testing can be provided in a brochure, video, or group educational session. Consent must be obtained before testing; and, prevention counseling must be provided to those who are at risk for HIV.

The basic flow of the initial rapid test counseling session is:

1) introduction, information, and consent,
2) obtain specimen and perform test,
3) prevention counseling (while test is running), and
4) provide results, additional counseling, and referrals.

SINGLE-SESSION COUNSELING ELEMENTS

1) ESTABLISH INITIAL RAPPORT

2) PROVIDE INFORMATION

3) OBTAIN INFORMED CONSENT

(Perform Fingerstick Blood Draw, and Initiate OraQuick Rapid HIV-1 Antibody Testing)

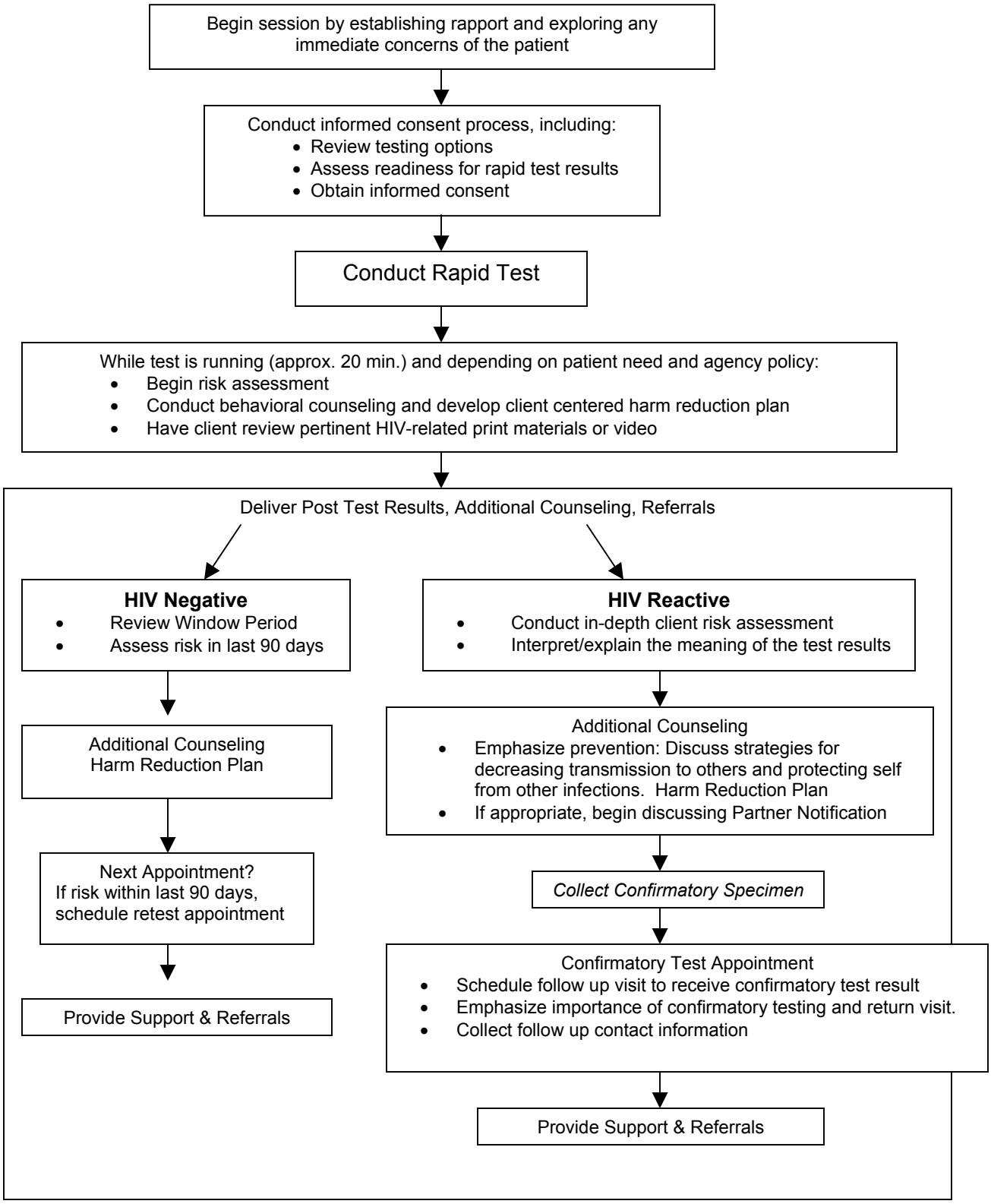
4) PROVIDE CLIENT-CENTERED PREVENTION COUNSELING

5) PROVIDE RESULTS, ADDITIONAL COUNSELING, AND REFERRALS

- Non-reactive = Negative.
- Reactive = Preliminary Reactive (requires confirmatory testing)

(For Preliminary Reactive, collect specimen for confirmatory testing and schedule a return appointment for the client to receive results.)

SINGLE SESSION COUNSELING FLOWCHART



PROVIDING INFORMATION

Providing information is an important component of the session. For a client to give "informed consent" the client must have a basic understanding of HIV and the Rapid HIV-1 Antibody test.

Because clients must understand this information before they can give informed consent, the CDC guidance recommends and Washington State law *requires* that providers conducting HIV testing also provide clients with information about the test, test results, anonymous and confidential testing options, etc.

This information can be provided either in a face-to-face meeting with a counselor or in a pamphlet, brochure, or video. If a pamphlet, brochure, or video is used to convey this information, the counselor should also check in with the client to assure s/he understands the information.

Clients tested with a rapid HIV test must be given the same types of information recommended for those tested with a standard EIA:

- Information about the HIV test, its benefits and consequences.
- Ways HIV is transmitted and how it can be prevented.
- The meaning of the test results in explicit, understandable language.
- Where to obtain further information and, if applicable, HIV prevention counseling.
- Where to obtain other services including, if applicable, treatment.

In addition, clients tested with rapid HIV tests must be:

- Advised that their rapid test results will be available during the same visit.
- Informed that confirmatory testing is needed if the rapid test result is reactive.

The Oraquick package insert also requires that individuals being tested with the rapid test must receive the "Subject Information" pamphlet prior to specimen collection.

SUGGESTED LANGUAGE

Information describing the rapid test and the window period should be clear, concise, and consistent, to avoid both individual client confusion and mixed and unclear messages about the rapid test process disseminating into the community.

RAPID TEST

"The rapid test is a same-day test. You will receive your results today."

WINDOW PERIOD

"This test looks for HIV antibodies. It can take up to 3 months to develop these antibodies. This test will tell you whether or not you were infected as of 3 months ago. If you engaged in risk behavior during the last 3 months, and you became infected, that ***may not*** *show up on this test. You'll need a test a full 3 months from the last time you put yourself at risk to be sure."*

ASSURING INFORMED CONSENT

As with the standard HIV test, Washington State law requires that providers conducting HIV tests obtain or ensure informed consent for HIV testing.

This consent must be:

- obtained **prior** to performing the test,
- **specific to HIV**, and
- **separate** from other consents (WAC 246-100-207 (1) (b) *(with the exception of HIV testing of pregnant women).*

For a client to give "informed consent", the client must understand the basic information about HIV and the Rapid HIV-1 Antibody test (what the test is, what the benefits and drawbacks of testing are, how HIV is transmitted, etc). In addition, Washington State law also requires that providers conducting HIV testing provide clients with this basic information about the test, test results, anonymous and confidential testing options, reporting requirements, etc. (see: Appendix O, for WAC 246-100-209).

A written consent form can fulfill both of these requirements (see: Appendix M, for examples of written consent forms). These example consent forms are designed to fulfill both the requirement to provide information and the requirement to obtain consent.

All confidential testing sites should use a written consent form and retain such consent forms to document provision of information and the consent process.

Anonymous testing programs should also use a written consent. In such a case, the clients sign the consent with initials or a code name. Again, these signed consents should be retained to document the provision of information and the consent process.

Note: Washington State law does not require that the consent is in writing. Therefore, it is an option for test sites to obtain verbal consent. Verbal consent is often used in anonymous testing situations. If verbal consent is used, procedures and protocols should clearly identify and describe the process of how counselors should document consent in their client notes.

Because consent must be obtained *prior* to ordering or prescribing the test, counselors must obtain consent *before* they conduct the finger stick and initiate the rapid test.

PREVENTION COUNSELING

HIV Prevention Counseling should be conducted with the rapid HIV test when individuals have a risk for HIV infection. Counseling must follow Washington State law. The Washington State HIV Counseling, Testing, and Partner Notification Guide can help agencies prepare for counseling with rapid testing.

Fundamentals of HIV prevention counseling with rapid HIV tests include:

- Keep the session focused on HIV risk reduction.
- Include an in-depth, personalized risk assessment.
- Acknowledge and provide support for positive steps already made.
- Clarify critical, rather than general, misconceptions about HIV risk.
- Negotiate a concrete, achievable, behavior-change step that will reduce HIV risk.
- Seek flexibility in the counseling technique and process, avoiding a "one-size-fits-all" approach.

The primary goal of HIV prevention counseling should be to assist the client to change their risk taking behaviors. To achieve this goal, counselors must quickly establish trust and rapport, explain concepts simply, skillfully draw-out client concerns, and assist the client in negotiating steps to reduce their risk. A competent counselor can accomplish all of this in the twenty to thirty-minute conversation conducted before sharing the test results with the client.

Most counseling with rapid testing is a single session conducted while the test is being performed. Counseling should be primarily conducted during the period after consent is obtained (and after the testing process has begun) and before the test results are read.

Agencies should develop and use Prevention Counseling protocols that include at minimum some form of the following (see: Appendix J, for an example of a Rapid Testing protocol):

1) Enhancing Client's Self-Perception of Risk
2) Exploration of the Specifics of the Most Recent Exposure Incident
3) Review of Previous Risk Reduction Experiences
4) Exploration of Risk Incident and Risk Patterns
5) Negotiation of a Risk Reduction Plan
6) Identify Sources of Support and Provide Additional Referrals

Additional guidance to be considered when providing HIV counseling with rapid testing:

- Washington State Partner Counseling and Referral Services Guide
- Centers for Disease Control and Prevention (CDC) Revised Guidelines for HIV Counseling, Testing, and Referral
- http://www.cdc.gov/hiv/rapid_testing/ (for updates and additional suggestions for rapid test counseling protocols.)

Note: Most agencies funded to provide Rapid HIV-1 Antibody testing with Federal High-risk HIV Prevention dollars must follow the 6-step counseling protocol taught in the Washington State HIV Prevention Counseling Course. Call Claudia Catastini, Department of Health (360-236-3422) to verify if staff must attend that course and use that counseling protocol.

PROVIDING RESULTS

PROVIDING NEGATIVE RESULTS

The counselor should provide the initial test result in simple terms, avoiding technical jargon. The client may be very relieved at receiving the negative test result. The counselor should allow the client to experience his/her pleasure at not being infected while gently underscoring the need for behavior change in order for the client to remain negative. The counselor should cautiously explore feelings and beliefs the client has about his/her negative test results, particularly in the context of the risk behavior the client has described thus far in the session. The counselor should be alert to the possibility that the client may experience some dis-inhibition (i.e., feel more inclined to engage in risky behavior) in response to the results. The client may believe the test result is an indication that he/she has, thus far, made the "right choices." It is often helpful for the counselor to underscore the fact that the negative test result does not indicate that the client's sex/needle-share partner(s) are not infected. There is a slight possibility that a recent risk behavior (especially in the last month) may have resulted in the client becoming infected without the infection being indicated in this test result. However, both counselor and client should be reminded that the current result represents all other, sometimes years of previous risk behavior. Counselors must be very careful with their "retest message." If there were no significant risks in the previous 3 months, then no additional test is indicated unless the client has a later exposure to HIV. If there was a very recent and significant risk exposure, there is a chance that the client could have been infected by that exposure. The counselor should remember that the risk of infection from a single exposure, when the partner is known to be infected, is relatively small (<1 – 8%). The counselor should avoid technical discussions of this information and recommend, when necessary, a specific time for possible retest linked to a specific previous date of exposure. In summary, a brief explanation of the possible need for retesting is sometimes, with some clients, important, but this should not be over-emphasized. Too much attention to retesting takes away attention from the risk reduction process and often inaccurately diminishes the meaning of the HIV negative result.

NEGATIVE TEST RESULTS

During the initial visit, the provider can definitively tell clients whose rapid HIV test result is negative that they are not infected, unless they have had a recent (within 3 months) known or possible exposure to HIV. Retesting should be recommended for these clients because sufficient time needs to elapse in order before antibodies develop that can be detected by the test.

SUGGESTED LANGUAGE

- **Negative Test Result (no risk behavior within the last 3 months):**
  "Your test results are negative. You do not have HIV."

- **Negative Test Result (risk behavior within the last 3 months):**
  "Your test results are negative. This means that you were uninfected as of 3 months ago. The last risk behavior you said you engaged in, on (date), may not show up on this test. You need another test a full 3 months from (date) to be sure that you are uninfected."

PROVIDING PRELIMINARY REACTIVE RESULTS

The priority for this component of the session is to ensure that the client correctly understands the test result. The counselor should provide the initial test result in simple terms, avoiding technical jargon. The counselor should choose language that reflects the likelihood that the client is actually infected with HIV. In choosing phrases to convey the meaning of the initial test result, the counselor should consider the client's reported risk behavior. The counselor should be clear with the client that the information provided by the client in the beginning of the session, particularly the risk assessment, may help influence the client and counselor's understanding of the results. This may provoke the client to offer additional details concerning risk that he/she was reluctant to address previously. The counselor should remind the client that this result is preliminary and review the process of supplemental testing. The counselor must emphasize the need for supplemental testing, as well as the importance of the client returning for additional results, and identify sources of support while awaiting test results. The counselor should acknowledge that receiving this initial result can be disconcerting, elicit feedback from the client as to how he/she is feeling about the result, and provide appropriate support.

REACTIVE TEST RESULTS

For all clients with a preliminary reactive rapid HIV test result, it is essential to:

- Explain the meaning of the preliminary reactive test result in simple terms, avoiding technical jargon.
- Emphasize the importance of confirmatory testing and schedule a return visit for the confirmatory test results.
- Underscore the importance of taking precautions to avoid the possibility of transmitting infection to others while awaiting results of confirmatory testing.

SUGGESTED LANGUAGE

"Your preliminary test result is reactive.
We won't know for sure if you are infected with HIV until we get the results from your confirmatory test.
In the meantime, take precautions to protect yourself and avoid transmitting the virus to others."

See: Appendix K "PRELIMINARY REACTIVE COUNSELING MESSAGES", for further suggestions of language to use in counseling sessions for preliminary reactive clients.

CONFIRMATORY SPECIMEN COUNSELING

Counselors should assure that preliminary positive clients are told that they must have a confirmatory test to be sure of their results. Counselors should stress to the client the importance of returning for the results of the confirmatory test.

Set appointment to obtain HIV confirmatory results.

a) Write appointment date and time on appointment card, and give it to the client.

b) If confirmed positive, client will be offered referral to HIV case management services.

c) If confirmed positive, the HIV medical provider or counselor will follow up on partner notification interview to assure that the client's partners have been notified of possible exposure to HIV.

d) Offer informational packet to the client as another resource for information and referrals.

e) Whether HIV-infected or not, additional support referrals should be provided, as needed.

Review plans and answer any questions.

a) Review support plans.

b) Review plan/appointment for obtaining confirmatory HIV test.

c) If client agrees, obtain/verify phone number or other contact information to permit pro-active communication with the client about outcome of confirmatory testing.

d) Review plan for partner notification.

CONFIRMATORY RESULT COUNSELING

Follow Washington State law and refer to the Washington State HIV/AIDS Counseling and Partner Notification Guide and the Washington State HIV Partner Counseling and Referral Services Guide when developing policies and procedures for negative, indeterminate, and positive confirmatory test result counseling.

Positive Confirmatory Test Results

The confirmatory test is required to be **positive** before the counselor can inform the client they are infected with HIV. Therefore, the confirmatory positive test result session is the session in which the counselor informs the client that they are infected with HIV. Protocols for confirmatory positive results counseling must include informing the client of the test results and what they mean to the client; prevention counseling; partner notification assistance; a reminder not to donate organs; and, referrals for medical care, additional prevention services, and appropriate support. An example protocol for a positive confirmatory test result session:

a) Re-introduce yourself, and welcome client back to testing space.
b) Invite the client to sit down and state the purpose of the session.
c) Reveal and identify test results clearly and simply for the client.
d) Review meaning of the results. Confirmed Positive:
   - means that a person is infected with HIV,
   - does not necessarily mean that a person has AIDS; additional assessment and testing is needed to make an AIDS diagnosis; follow-up medical assessment important for care,
   - must not donate organs or body parts
   - inform health care providers of HIV infection when seeking care (to get appropriate care)
e) Counseling/support for clients with confirmed HIV positive test results
   - Allow the client time to absorb the meaning of the confirmed HIV positive test result.
   - Explore client's understanding of confirmed HIV positive test result.
   - Assess how client is coping with this new information.
   - Identify and discuss the client's concerns and answer client's questions.
   - Acknowledge the challenges of dealing with a newly identified HIV infection.
   - Negotiate/reaffirm a risk-reduction plan.
   - Problem solve issues concerning the plan including disclosure of HIV status to partners before possible risk activity involving that partner.
   - Confirm with the client that the plan is reasonable and acceptable.
   - Assess for risk of suicide and homicide.
   - Re-assess and discuss support options for coping with confirmed HIV positive test result.
   - Assist client to establish a support plan for the next twenty-four hours and the next week.
f) Partner notification for clients with confirmed HIV positive test results
   - Identify any sex or needle-sharing partners that may have been exposed to HIV by the client.
   - Determine which of these partners will be notified of possible exposure to HIV by the client or by Public Health, and determine which are unlocatable.
   - Collect names and other identifying information of the exposed partners who will be notified by Public Health. Pass this information on to the appropriate person.
g) If confidential test, remind client of the requirement for case reporting
h) Make referrals for clients with confirmed HIV positive test results
   - Make an appointment for an initial health assessment.
   - Offer referrals for emotional support (e.g., Crisis Clinic), as needed.
   - Refer for case management services.
   - Refer for additional support and assistance with partner notification.
   - Refer for additional support for prevention and risk reduction efforts.
   - If suicidal, assist with active referral for a mental health evaluation.

PARTNER COUNSELING AND REFERRAL SERVICES

The same laws regarding partner notification for standard HIV testing apply for rapid HIV testing (WAC 246-100; RCW 70.24).

- At pretest, clients must be informed that if they are confirmed HIV positive, their partners must be notified.

- At the positive confirmatory result counseling session, clients must be informed that their partners must be notified and assistance must be offered or arranged by the provider.

Therefore, it is appropriate to inform clients at the preliminary reactive rapid test result session that if the confirmatory results are positive, partners must be notified. However, partner elicitation should only commence at the positive confirmatory result counseling session.

Partner elicitation can be performed by the counselor providing the results, or can be arranged through active referral to be provided by the local health department. The recommended method is to have someone from the local health department on site and available to meet with the infected client at the time the confirmatory results are provided to the client.

Field work (looking for partners) and the notification of partners should be conducted by the local health department. Agencies can confidentially report identifying and locating information about partners to the local health department without giving out any information about the client who tested positive.

All locating and identifying partner information must be destroyed at time of notification of the partner, or in 90 days, whichever comes first. Agency policies and procedures should include clear processes and timelines for the destruction of partner identifying and locating information.

Agencies should set policies and procedures regarding partner elicitation and arrange interagency agreements with their local health department to assure the provision of partner elicitation counseling and the notification of partners.

Agencies should follow the Washington State HIV Partner Counseling and Referral Services (PCRS) Guide when developing policies and procedures for partner notification. This guide is available through the Washington State Department of Health. Call Claudia Catastini at (360) 236-3422 for copies of this guide.

SPECIAL CONSIDERATIONS FOR COUNSELING

Anonymous Testing

For those sites that offer anonymous rapid testing, counselors should both offer and *strongly encourage* **confidential** confirmatory testing. Confidential confirmatory testing will assure that clients receive confirmatory results, partner counseling and referral services, and referral into appropriate case management and care services. Agencies should refer locating information on confidential clients (that do not return for their positive HIV results) to local health department staff to locate and notify them of their results. WAC 246-100-072 allows for agencies to confidentially provide local health department staff with locating information for clients in order for local health department staff to notify them of their positive results, provide partner notification counseling, and refer them to care.

For clients that choose to remain anonymous for confirmatory testing, the CDC recommends that counselors obtain detailed locating information on the clients so that they can be contacted (if they fail to return for their results), notified of their results, and encouraged to come in for care and follow-up. Counselors must explain this rationale for collecting locating information to the client so the client understands that, although they tested anonymously, the locating information will allow for notification of their results if they do not return. If anonymous clients (who provided locating information) do not return for results, agencies should consult with local health department staff regarding locating and notifying clients.

Placement of Test Kit During Counseling Session

Because the actual HIV test is begun during the session and runs through the session, a decision must be made whether or not the client and counselor will watch the test run. It is recommended that the counselor initiates the test and then puts it aside, out of view, until at least 20 minutes are up. This allows for the client and the counselor to focus on the counseling needs of the client, rather than watching the test kit. In order to assure that the test is read at the appropriate time, the counselor starts a stop-watch or timer when the test is initiated. Then, when the alarm goes off in 20 minutes, the counselor brings the test kit into view and both the client and counselor read the results at the same time.

Off-site Counseling

Assure in off-site counseling situations that confidentiality will be maintained. Counseling sessions must be private and confidential. Test results and records must be transported and maintained in a confidential manner.

Age of Consent Law

The same laws regarding age of consent for standard HIV testing apply for rapid HIV testing. A child must be 14 years of age to provide independent consent for an HIV test. Note: because no clinical data is available to demonstrate the performance of OraQuick on persons under the age of 13, at this time it is not recommended to use OraQuick on persons under the age of 13.

Peer Counseling

If a counselor is a community member or “peer” counselor, special efforts should be made to assure the counselor’s understanding of, and commitment to adhere to, standards of ethics and boundaries with clients. In addition, because “peer” counselors can spend time off work attending events where they could be involved in activities with clients, protocols should be established, maintained, and monitored to assure that counselors adhere to professional standards of confidentiality. Agencies should provide clear guidance and necessary support.

APPENDICES

APPENDIX A: TRAINING LOG

The purpose of the Training Log is to assure documentation of training. The training log should be kept in the personnel file of the staff person. Staff should complete training before serving clients without direct supervision.

This log documents training completed (with the date completed). In addition, it allows for an observation procedure whereby a trainer or supervisor observes the staff person as they conduct the procedure. At observation, the supervisor or trainer evaluates whether or not the staff person's performance is a "pass" (adequate performance of procedure) or "no pass" (inadequate performance requiring corrective action and further training). If "pass", the staff person is ready to perform the procedure with clients. If "no pass" supervisor or trainer initiates a corrective action (usually further training and an additional observation). Corrective action is documented on this form.

When the staff person has completed training and achieved an "adequate performance" observation of the procedure, supervisor or trainer signs and dates "OK to Perform Activity."

Staff persons should not conduct procedures with clients until they can demonstrate adequate performance of the procedure.

* * * * * *

Having qualified, trained staff to perform and supervise OraQuick testing is one of the most important factors for ensuring accurate and reliable results.

Training is crucial to ensuring quality testing. Staff should be fully trained on how to perform their assigned tasks and responsibilities. Training should be documented for each staff member. The training program should include:

- How to store (and where applicable, transport) test kits and document storage temperatures.
- How to perform the test and controls, including procedures performed before, during, and after testing (including documentation of results and controls).
- Confirmatory specimen collection techniques: blood-draw and/or oral fluid collection.
- Counseling Protocols.
- Confidentiality and Ethics (including HIPPA).
- The use and importance of Universal (or Standard) Precautions/biohazard safety (OSHA/WISHA).

Staff should be required to sign a confidentiality statement before beginning work.

Rapid Testing Personnel Training and Procedure Checklist

Employee Name: _____

Training	Date Training Completed	Date Procedure Observed		If No Pass, Corrective Action Taken	Trainer or Supervisor OK to Perform Activity	
		Pass	No Pass		Signature	Date
Fingerstick						
Determination of Acceptable Testing Environment						
Temperature Documentation						
Quality Controls						
Documentation of Controls						
OraQuick Test Kit						
Documentation of Testing						
Result Documentation						
Confirmatory Specimen Collection						
Confirmatory Specimen Shipment						
Confirmatory Specimen Documentation						
Receive and Document Laboratory Results						
Test Completion and Clean-up						
Biohazard / OSHA/WISHA		**N/A**	**N/A**	**N/A**		
Confidentiality / HIPAA		**N/A**	**N/A**	**N/A**		
Explanation of Rapid Test						
Prevention Counseling						
Results Explanation						
Confirmatory Test Result Counseling						
Signed Statement Confidentiality		**N/A**	**N/A**	**N/A**		
Completed						
WA State Prevention Counseling Training (If Applicable)		**N/A**	**N/A**	**N/A**		
Read WAC 246-100 Requirements		**N/A**	**N/A**	**N/A**		

APPENDIX B: REFRIGERATOR TEMPERATURE LOG

The purpose of the Refrigerator Temperature Log is to document the temperature of the refrigerator used to store control and other specimens.

- Check and document refrigerator temperature each day.
- The temperature of the refrigerator should be maintained at 2°C to 8°C (35°F to 46°F).
- "Date" – write the date using numerical digits in the corresponding square.
- "Time" – write the time using military time notation (e.g., 0800, 1351)
- "Temperature" – write the temperature in the corresponding square as indicated on the thermometer inside the refrigerator.
- "Staff Initials" – write the initials of the staff member logging the temperature.
- If the refrigerator temperature is 1° to 2° outside of the acceptable range, adjust the refrigerator control accordingly and check the temperature again one hour.
- If the refrigerator temperature is more than 2° outside of the acceptable range, discard the control specimens.

Refrigerator Temperature Log

Acceptable Range: 2°C to 8°C or 35°F to 46°F

Location: _____ Month: _____

Date	Time	Temperature	Corrective Action/Comments	Staff Initials
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
21				
22				
23				
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25				
26				
27				
28				
29				
30				
31				

Supervisor/Director Review_____

APPENDIX C: AMBIENT TEMPERATURE LOG

The purpose of the Ambient Temperature Log is to document the temperature of the room where test kits are stored (if not refrigerated) and the area where the actual testing is performed.

- Check and document the ambient temperature of the test kit storage area each day.
- Check and document the ambient temperature of the testing area each day testing is done
- If there is a significant change in ambient temperature throughout the day, re-check and document.
- The ambient temperature should be maintained at 15°C to 27°C (59°F to 80 °F).
- "Date" – write the date using numerical digits in the corresponding square.
- "Time" – write the time using military time notation (e.g., 0800, 1351)
- "Temperature" – write the temperature in the corresponding square as indicated on the thermometer.
- "Staff Initials" – write the initials of the staff member logging the temperature.
- For the test kit storage area, if the temperature is more than 2 ° outside of the acceptable range, move the kits to an area where the temperature can be controlled and document on the log. Run external controls to verify that the test kits have not been compromised and document the results on the external control log.
- For the testing area, if the ambient temperature is 1° to 2 ° outside of the acceptable range, run the external controls and document the results on the external control log. Document the action taken on the temperature control log. Check the temperature again in one hour.
- If the temperature is more than 2 ° outside of the acceptable range, discontinue testing until the ambient temperature falls within the acceptable range.
- The supervisor or director should review and sign the ambient temperature logs on a monthly basis.

Ambient Temperature Log

Acceptable Range: 15-27°C or 59-80°F

Location: _____ Month: _____

DATE	Time	Temperature	Corrective Action/Comments (List location if different from main testing site)	Staff Initials
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
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25				
26				
27				
28				
29				
30				
31				

Supervisor/Director Review_____

APPENDIX D: EXTERNAL CONTROL LOG

The purpose of the External Control Log is to document performance of external positive and negative control tests using the OraQuick® Rapid HIV-1 Antibody Test.

Test positive and negative control tests under the following circumstances:

- New testing personnel perform the test.
- Opening a new test kit lot.
- A new shipment of test kits is received.
- The temperature of the test storage area falls outside of 2°C to 27°C (35°F to 80°F).
- The temperature of the testing area falls outside of 15°C to 27°C (59°F to 80°F).
- At periodic intervals as determined by the Test Site director.
- At new testing sites.

Document the control results and any corrective action taken when the results are not as expected. The director or supervisor should review on a monthly basis.

There are two different examples of External Control Logs in this APPENDIX.

EXAMPLE 1: EXTERNAL QUALITY CONTROL (QC) LOG

Kit Lot #_____ Date Opened_____ Expiration Date_____

Positive Control Lot #_____ Date Opened_____ Expiration Date_____

Negative Control Lot #_____ Date Opened_____ Expiration Date_____

DATE	Record Results		Corrective Action/Comments	Staff Initials
	Positive Control	Negative Control		

Supervisor/Director Review_____

EXAMPLE TWO: EXTERNAL CONTROL TEST LOG

Date	Time	Test Kit Lot #	Test Kit Expire Date	New Lot #, shipment?	Control Kit Lot#	Control Kit Expire Date	Date Controls Opened	Negative Control Result (-)	Positive Control Result (+)	Results OK? Y / N		If No, Corrective Action Taken	Performed By

Reviewed By: _____ Date: _____

APPENDIX E: TEST RESULT LOG

It is critical to carefully document the test process and the results. This will allow for quality assurance, insuring accuracy of results, and tracking results. Documentation of the test process includes:

- Client ID and Test Date
- Kit Lot # and Expiration Date
- Actual Test "Start" and "End" Times
- Test Result
- Internal Control Result
- The Time the Result is Given to the Client
- The Tester or Counselor Initials
- Confirmatory Testing
    - Tracking #
    - Specimen Type (oral or blood)
    - Result
    - Date Received
    - Date Given to Client

The purpose of the test result log is to document all associated information so that results can be tracked and errors are minimized.

Errors: Errors made by entering incorrect information or placing information in the wrong blank should be corrected by drawing a single line through the mistake(s) and initialing the line in the margin. Do not scribble over errors or use whiteout to cover them up - inspectors and lawyers assume that you are trying to hide something.

TEST RESULT LOG

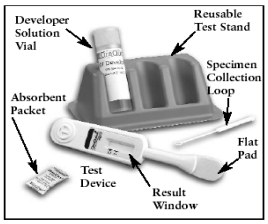
Client ID	Test Date	Kit Lot #	Kit Expire Date	Actual Test Incubation Times Start / End		Test Result Reactive (R) Nonreactive (N) Invalid (I)	Internal Control Result Valid (V) Invalid (I)	Time Result Given to Client	Tester Initials	Confirmatory Testing					Reviewed By/Date
										Tracking #	Specimen Type	Result	Date Received	Date Given to Client	

APPENDIX F: CONFIRMATORY SPECIMEN TRANSFER LOG

The purpose of the specimen transfer log is to track confirmatory specimen collection and shipping. Confirmatory results are logged on the test result log (see: APPENDIX E). This log assures that, if lab reports no specimen arrived, or cannot read specimen codes, there is a document to refer to. Specimen transfer logs can provide valuable information that can help minimize errors.

CONFIRMATORY SPECIMEN TRANSFER LOG

Specimen Tracking #	Client ID Code	OraQuick Test Result	Date Specimen Collected	Specimen Collected By	(√) Lab Requisition Completed	Sent To	Date Sent

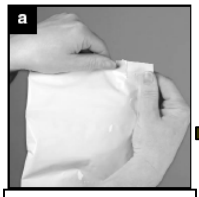


APPENDIX G: OraQuick® FLOWCHART

STEP I

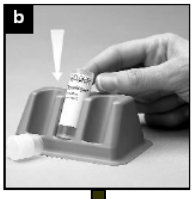
Give Client Subject Information → Bring Kit at Room Temp 15-17°C

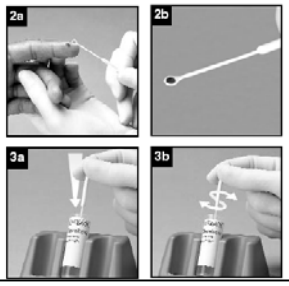
STEP II



Open Pouch

Place open developer vial in the stand





Collect and mix Sample in developer

Put paddle in the sample-developer mix.

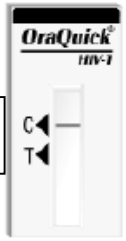
Let the Reaction occur for 20 min.

Read results after 20 min & no later than 60 min

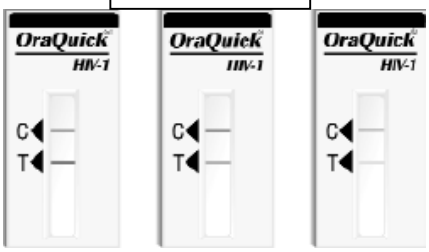
STEP III

Interpret Results as follows

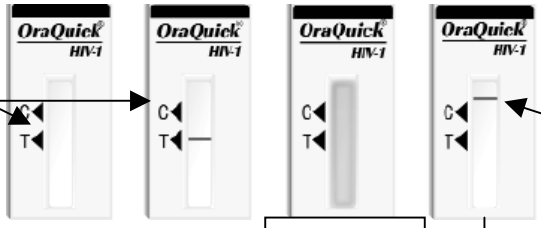
Non - Reactive



REACTIVE



No line in Control zone



Line outside the zone

Red smear

INVALID

APPENDIX H: RAPID TESTING - WHAT CAN GO WRONG

Storage of Test Kits

- If where tests kits are stored goes beyond the acceptable temperature range, it may affect the performance of the test. This may cause the test to indicate inaccurate results.
- If kits are stored refrigerated they must be warmed to room temperature before using, to ensure the test kit is performing properly. Forgetting to warm test kits to room temperature could cause inaccurate results.

Temperature of Testing Area

- If room temperature where the test is performed goes beyond the acceptable temperature range, it may affect the performance of the test. This may cause the test to indicate inaccurate results.

Specimen Collection

- Only fingerstick whole blood can be used with this testing device – other specimen types have not been validated by the manufacturer.
- Specimen collection loop must be filled completely or there may not be enough specimen to give a valid result. Incorrect specimen collection could cause inaccurate results.
- Developer solution should be pink after the specimen has been added or there may not be sufficient specimen to give a valid result. In sufficient specimen could cause inaccurate results.

Test Kit Components

- Test devices/developer solutions – must be from the same kit; interchanging lots numbers may give invalid results.
- Absorbent packet must be present in pouch containing the test device to insure that test device has not been adversely affected by excess moisture.
- Do not touch the flat pad on the test device – may contaminate the pad and interfere with test performance. Interference in test performance may cause inaccurate results.
- Do not cover the two holes in the back of the test device with labels or other materials – this could impair the fluid flow and cause an invalid result.
- Never reuse test components – they are made to be used only once. A test conducted with reused kit components could cause inaccurate results.

Reading the Test

- Adequate lighting must be available to read the test - faint lines may be missed if lighting is poor. This could cause misreading of results.
- Reading the test before 20 minutes or after 60 minutes could give invalid test results. Accurate timing of the test is critical for accurate results.
- Control line missing means test is invalid – fluid may have not migrated adequately through the test device. Missing an invalid test and reading results could cause inaccurate results.
- All lines must be within triangle area of “C” or “T” or test is invalid.
- Red background on test and control area means test is invalid.
- If external controls do not give expected results the test kits may not be functioning properly. In such a case, do not report patient results. Results could be invalid.

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APPENDIX I: MODEL EXPOSURE CONTROL PLAN

This Model Exposure Control Plan is intended to serve employers as an example exposure control plan which is required by the Bloodborne Pathogens Standard. A central component of the requirements of the standard is the development of an exposure control plan (ECP).

The intent of this model is to provide small employers with an easy-to-use format for developing a written exposure control plan.

Employers will need to adjust or adapt the model for their specific use.

The information contained in this publication is not considered a substitute for the OSH Act or any provisions of OSHA standards. It provides general guidance on a particular standard-related topic but should not be considered a definitive interpretation for compliance with OSHA requirements. The reader should consult the OSHA standard in its entirety for specific compliance requirements.

BLOODBORNE PATHOGENS EXPOSURE CONTROL PLAN

POLICY
The *(Facility Name)* is committed to providing a safe and healthful work environment for our entire staff. In pursuit of this endeavor, the following exposure control plan (ECP) is provided to eliminate or minimize occupational exposure to bloodborne pathogens in accordance with OSHA standard 29 CFR 1910.1030, "Occupational Exposure to Bloodborne Pathogens."

The ECP is a key document to assist our firm in implementing and ensuring compliance with the standard, thereby protecting our employees. This ECP includes:

- Determination of employee exposure
- Implementation of various methods of exposure control, including:
  - Universal precautions
  - Engineering and work practice controls
  - Personal protective equipment
  - Housekeeping
- Hepatitis B vaccination
- Post-exposure evaluation and follow-up
- Communication of hazards to employees and training
- Record keeping
- Procedures for evaluating circumstances surrounding an exposure incident
- The methods of implementation of these elements of the standard are discussed in the subsequent pages of this ECP.

PROGRAM ADMINISTRATION
(*Name of responsible person or department*) is (are) responsible for the implementation of the ECP. (*Name of responsible person or department*) will maintain, review, and update the ECP at least annually, and whenever necessary to include new or modified tasks and procedures. Contact location/phone number: _____

Those employees who are determined to have occupational exposure to blood or other potentially infectious materials (OPIM) must comply with the procedures and work practices outlined in this ECP.

Name of responsible person or department) will maintain and provide all necessary personal protective equipment (PPE), engineering controls (e.g., sharps containers), labels, and red bags as required by the standard. (*Name of responsible person or departmen*t) will ensure that adequate supplies of the aforementioned equipment are available in the appropriate sizes. Contact location/phone number:_____

(*Name of responsible person or department*) will be responsible for ensuring that all medical actions required are performed and that appropriate employee health and OSHA records are maintained. Contact location/phone number: _____

(*Name of responsible person or department*) will be responsible for training, documentation of training, and making the written ECP available to employees, OSHA, and NIOSH representatives. Contact location/phone number: _____

EMPLOYEE EXPOSURE DETERMINATION
The following is a list of all job classifications at our establishment in which **all** employees have occupational exposure:

JOB TITLE DEPARTMENT/LOCATION
(Example: Phlebotomists) (Clinical Lab)

_____ _____

_____ _____

_____ _____

The following is a list of job classifications in which **some** employees at our establishment have occupational exposure. Included is a list of tasks and procedures, or groups of closely related tasks and procedures, in which occupational exposure may occur for these individuals:

JOB TITLE DEPARTMENT/LOCATION TASK/PROCEDURE
(Example: Housekeeper - Environmental Services - Handling Regulated Waste)

_____ - _____ - _____

*Part-time, temporary, contract and per diem employees are covered by the standard. How the provisions of the standard will be met for these employees should be described in the EC*P.

METHODS OF IMPLEMENTATION AND CONTROL

Universal Precautions
All employees will utilize universal precautions.

Exposure Control Plan
Employees covered by the bloodborne pathogens standard receive an explanation of this ECP during their initial training session. It will also be reviewed in their annual refresher training. All employees have an opportunity to review this plan at any time during their work shifts by contacting (*Name of responsible person or department*). If requested, we will provide an employee with a copy of the ECP free of charge and within 15 days of the request. (*Name of responsible person or department*) is responsible for reviewing and updating the ECP annually or more frequently if necessary to reflect any new or modified tasks and procedures which affect occupational exposure and to reflect new or revised employee positions with occupational exposure.

Engineering Controls and Work Practices
Engineering controls and work practice controls will be used to prevent or minimize exposure to bloodborne pathogens. The specific engineering controls and work practice controls used are listed below:

- _*(For example: non-glass capillary tubes, SESIPs, needleless systems)*
- _____
- _____

Sharps disposal containers are inspected and maintained or replaced by (*Name of responsible person or department*) every *(list frequency)* or whenever necessary to prevent overfilling.

This facility identifies the need for changes in engineering control and work practices through: *(List Examples: Review of OSHA records, employee interviews, committee activities, etc.)*

We evaluate new procedures or new products regularly by: *(Describe the process, literature reviewed, supplier info, products considered).*

Both front line workers and management officials are involved in this process: *(Describe how employees will be involved).*

(Name of responsible person or department) will ensure effective implementation of these recommendations.

Personal Protective Equipment (PPE)

PPE is provided to our employees at no cost to them. Training is provided by (*Name of responsible person or department*) in the use of the appropriate PPE for the tasks or procedures employees will perform.

The types of PPE available to employees are as follows: *(Ex., gloves, eye protection, etc*.)

PPE is located *(List location*) and may be obtained through *(Name of responsible person or department*) .(Specify how employees are to obtain PPE, and who is responsible for ensuring that it is available.)

All employees using PPE must observe the following precautions:

- Wash hands immediately or as soon as feasible after removal of gloves or other PPE.
- Remove PPE after it becomes contaminated, and before leaving the work area.
- *Used PPE may be disposed of in _____(List appropriate containers for storage, laundering, decontamination, or disposal.)*
- Wear appropriate gloves when it can be reasonably anticipated that there may be hand contact with blood or OPIM, and when handling or touching contaminatedD-6 items or surfaces; replace gloves if torn, punctured, contaminated, or if their ability to function as a barrier is compromised.
- Utility gloves may be decontaminated for reuse if their integrity is not compromised; discard utility gloves if they show signs of cracking, peeling, tearing, puncturing, or deterioration.
- Never wash or decontaminate disposable gloves for reuse.
- Wear appropriate face and eye protection when splashes, sprays, spatters, or droplets of blood or OPIM pose a hazard to the eye, nose, or mouth.
- Remove immediately or as soon as feasible any garment contaminated by blood or OPIM, in such a way as to avoid contact with the outer surface.

The procedure for handling used PPE is as follows: *(may refer to specific agency procedure by title or number and last date of review)*

_____

_____

(For example, how and where to decontaminate face shields, eye protection, resuscitation equipment)

Housekeeping

Regulated waste is placed in containers which are closable, constructed to contain all contents and prevent leakage, appropriately labeled or color-coded (see Labels), and closed prior to removal to prevent spillage or protrusion of contents during handling.

The procedure for handling **sharps disposal containers** is: *(may refer to specific agency procedure by title or number and last date of review)*

_____
_____

The procedure for handling **other regulated waste** is: *(may refer to specific agency procedure by title or number and last date of review)*

_____
_____

Contaminated sharps are discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and labeled or color-coded appropriately. Sharps disposal containers are available at _____(*must be easily accessible and as close as feasible to the immediate area where sharps are use*d).

Bins and pails (e.g., wash or emesis basins) are cleaned and decontaminated as soon as feasible after visible contamination.

Broken glassware which may be contaminated is picked up using mechanical means, such as a brush and dustpan.

Laundry

The following contaminated articles will be laundered by this company:

_____ _____
_____ _____

Laundering will be performed by *(Name of responsible person or department)* at *(time and/or locatio*n).

The following laundering requirements must be met:

- handle contaminated laundry as little as possible, with minimal agitation
- place wet contaminated laundry in leak-proof, labeled or color-coded containers before transport. Use *(red bags or bags marked with biohazard symbo*l)_____ for this purpose.
- wear the following PPE when handling and/or sorting contaminated laundry:
- *(List appropriate PP*E)_____

Labels

The following labeling method(s) is used in this facility:

EQUIPMENT TO BE LABELED LABEL TYPE (size, color, etc.)
(e.g., specimens, contaminated laundry, etc.)(red bag, biohazard label, etc.)

_____ _____
_____ _____

(Name of responsible person or department) will ensure warning labels are affixed or red bags are used as required if regulated waste or contaminated equipment is brought into the facility. Employees are to notify _____ if they discover regulated waste containers, refrigerators containing blood or OPIM, contaminated equipment, etc. without proper labels.

Equipment, Environment and Work Surfaces

1. Contaminated work surfaces shall be decontaminated with an appropriate disinfectant:
    a. After completion of procedures;
    b. Immediately or as soon as feasible when surfaces are clearly contaminated or after any spill of blood or other potentially infectious materials
    c. At the end of the work shift, if the surface may have become contaminated since the last routine cleaning.

2. Spills of blood should be decontaminated with freshly diluted (1:10) bleach, or with an EPA – approved disinfectant. Appropriate gloves, gowns and masks should be worn if necessary to protect clothing and employee during cleaning and decontamination procedures. Cover spill with paper towels or other absorbent material and flood with diluted bleach solution. Let stand for at least 10 minutes. Clean up with more paper towels. Dispose of as infectious waste. With large spills of culture or concentrated infectious agents in the laboratory, the contaminated area should be flooded with a liquid germicide before cleaning, then decontaminated with fresh germicidal chemical.

3. Protective coverings, such as plastic wrap, aluminum foil or imperviously- backed absorbent paper used to cover equipment and environmental surfaces, shall be removed and replaced as soon as feasible, when they become openly contaminated or at the end of the workshift if they "may" have become contaminated.

4. Broken glassware, which may be contaminated, should not be picked up directly with the hands. It must be soaked with disinfectant and then cleaned up using mechanical means, such as a brush and dustpan, tongs or forceps.

HEPATITIS B VACCINATION

(Name of responsible person or department) will provide training to employees on hepatitis B vaccinations, addressing the safety, benefits, efficacy, methods of administration, and availability.

The hepatitis B vaccination series is available at no cost after training and within 10 days of initial assignment to employees identified in the exposure determination section of this plan. Vaccination is encouraged unless: 1) documentation exists that the employee has previously received the series, 2) antibody testing reveals that the employee is immune, or 3) medical evaluation shows that vaccination is contraindicated.

However, if an employee chooses to decline vaccination, the employee must sign a declination form. Employees who decline may request and obtain the vaccination at a later date at no cost. Documentation of refusal of the vaccination is kept at *(List location or person responsible for this record keeping).*

Vaccination will be provided by (List *Health care Professional who is responsible for this part of the pla*n) at *(location)*.

Following the medical evaluation, a copy of the health care professional's Written Opinion will be obtained and provided to the employee. It will be limited to whether the employee requires the hepatitis vaccine, and whether the vaccine was administered.

POST-EXPOSURE EVALUATION AND FOLLOW-UP

Should an exposure incident occur, contact *(Name of responsible person)* at the following number:_____.

An immediately available confidential medical evaluation and follow-up will be conducted by *(Licensed health care professional)*. Following the initial first aid (clean the wound, flush eyes or other mucous membrane, etc.), the following activities will be performed:

- Document the routes of exposure and how the exposure occurred.
- Identify and document the source individual (unless the employer can establish that identification is infeasible or prohibited by state or local law).
- Obtain consent and make arrangements to have the source individual tested as soon as possible to determine HIV, HCV, and HBV infectivity; document that the source individual's test results were conveyed to the employee's health care provider.
- If the source individual is already known to be HIV, HCV and/or HBV positive, new testing need not be performed.
- Assure that the exposed employee is provided with the source individual's test results and with information about applicable disclosure laws and regulations concerning the identity and infectious status of the source individual (e.g., laws protecting confidentiality).
- After obtaining consent, collect exposed employee's blood as soon as feasible after exposure incident, and test blood for HBV and HIV serological status * If the employee does not give consent for HIV serological testing during collection of blood for baseline testing, preserve the baseline blood sample for at least 90 days; if the exposed employee elects to have the baseline sample tested during this
- Waiting period, perform testing as soon as feasible.

ADMINISTRATION OF POST-EXPOSURE EVALUATION AND FOLLOW-UP

(Name of responsible person or department) ensures that health care professional(s) responsible for employee's hepatitis B vaccination and post-exposure evaluation and follow-up are given a copy of OSHA's bloodborne pathogens standard.

(Name of responsible person or department) ensures that the health care professional evaluating an employee after an exposure incident receives the following:

- a description of the employee's job duties relevant to the exposure incident
- route(s) of exposure
- circumstances of exposure
- if possible, results of the source individual's blood test
- relevant employee medical records, including vaccination status

(Name of responsible person or department) provides the employee with a copy of the evaluating health care professional's written opinion within 15 days after completion of the evaluation.

PROCEDURES FOR EVALUATING THE CIRCUMSTANCES SURROUNDING AN EXPOSURE INCIDENT

(Name of responsible person or department) will review the circumstances of all exposure incidents to determine:

- engineering controls in use at the time
- work practices followed
- a description of the device being used (including type and brand)
- protective equipment or clothing that was used at the time of the exposure incident *(gloves, eye shields, etc.)*
- location of the incident *(O.R., E.R., patient room, etc.)*
- procedure being performed when the incident occurred
- employee's training

(Name of Responsible Person) will record all percutaneous injuries from contaminated sharps in the Sharps Injury Log.

If it is determined that revisions need to be made, *(Responsible person or department*) will ensure that appropriate changes are made to this ECP. *(Changes may include an evaluation of safer devices, adding employees to the exposure determination list, etc.)*

EMPLOYEE TRAINING

All employees who have occupational exposure to bloodborne pathogens receive training conducted by *(Name of responsible person or department)*. *(Attach a brief description of their qualifications.)*

All employees who have occupational exposure to bloodborne pathogens receive training on the epidemiology, symptoms, and transmission of bloodborne pathogen diseases. In addition, the training program covers, at a minimum, the following elements:

- a copy and explanation of the standard
- an explanation of our ECP and how to obtain a copy
- an explanation of methods to recognize tasks and other activities that may involve exposure to blood and OPIM, including what constitutes an exposure incident
- an explanation of the use and limitations of engineering controls, work practices, and PPE
- an explanation of the types, uses, location, removal, handling, decontamination, and disposal of PPE
- an explanation of the basis for PPE selection
- information on the hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine will be offered free of charge
- information on the appropriate actions to take and persons to contact in an emergency involving blood or OPIM
- an explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available

- information on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident
- an explanation of the signs and labels and/or color coding required by the standard and used at this facility
- an opportunity for interactive questions and answers with the person conducting the training session.

Training materials for this facility are available at _____.

RECORDKEEPING

Training Records
Training records are completed for each employee upon completion of training. These documents will be kept for at least **three years** at *(Name of responsible person or location of records*).

The training records include:
- the dates of the training sessions
- the contents or a summary of the training sessions
- the names and qualifications of persons conducting the training
- the names and job titles of all persons attending the training
- sessions

Employee training records are provided upon request to the employee or the employee's authorized representative within 15 working days. Such requests should be addressed to *(Name of Responsible person or department*).

Medical Records
Medical records are maintained for each employee with occupational exposure in accordance with 29 CFR 1910.1020, "Access to Employee Exposure and Medical Records."

(Name of Responsible person or department) is responsible for maintenance of the required medical records. These **confidential** records are kept at *(List location*) for at least the **duration of employment plus 30 year**s.

Employee medical records are provided upon request of the employee or to anyone having written consent of the employee within 15 working days. Such requests should be sent to *(Name of responsible person or department and address*).

OSHA Record keeping
An exposure incident is evaluated to determine if the case meets OSHA's Record keeping Requirements (29 CFR 1904). This determination and the recording activities are done by *(Name of responsible person or department*).

Sharps Injury Log
In addition to the 1904 Record keeping Requirements, all percutaneous injuries from contaminated sharps are also recorded in the Sharps Injury Log. All incidences must include at least:
- the date of the injury
- the type and brand of the device involved

- the department or work area where the incident occurred
- an explanation of how the incident occurred.

This log is reviewed at least annually as part of the annual evaluation of the program and is maintained for at least five years following the end of the calendar year that they cover. If a copy is requested by anyone, it must have any personal identifiers removed from the report.

HEPATITIS B VACCINE DECLINATION (MANDATORY)

I understand that due to my occupational exposure to blood or other potentially infectious materials I may be at risk of acquiring hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with hepatitis B vaccine, at no charge to myself. However, I decline hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with hepatitis B vaccine, I can receive the vaccination series at no charge to me.

Signed:__(*Employee Name*)_____

Date:_____

This Bloodborne Pathogens Hazard Communication Plan has been reviewed and approved for use without modification. The facilities and precautions are compatible with current knowledge and regulations at this time:

Review
Date/Signature_____

Review
Date/Signature_____

Review
Date/Signature_____

Review
Date/Signature_____

APPENDIX J: RAPID TESTING COUNSELING PROTOCOL

1) Establish initial rapport with client

a) Welcome client to testing space.
b) Introduce self.
c) Explain role as counselor.
d) Explain parameters of the counseling and testing session.

2) Provide Information - Explain OraQuick Rapid HIV-1 Antibody Testing process

a) Anonymous and confidential options.
b) Specimen is blood obtained through fingerstick.
c) Results can be read as soon as 20 minutes, no later than 60 minutes.
d) Non-reactive, "negative" results are conclusive. This means you were uninfected 3-months ago. Risk activity during the past 3-months may not show up on this test.
e) Reactive results are preliminary.
Preliminary reactive results require a confirmatory test.
- venipuncture or oral fluid sample collection, and
- attendance at a follow-up confirmatory result session in one week.

3) Obtain informed consent for Rapid HIV Testing

a) Review Key Points
- *Human Immunodeficiency Virus (HIV) causes Acquired Immunodeficiency Syndrome (AIDS).*
- *The test measures HIV antibodies (the body's reaction to the virus), not the virus itself.*
- *Negative test results indicate no evidence of HIV infection three months before the test.*
- *Preliminary reactive results are preliminary until confirmed; once confirmed, positive test results mean that the person tested is infected with HIV and can infect others.*
- *Benefits of being tested include: i) determining a treatment course, if positive, and ii) being reassured and relieved, if negative. (If no risk behavior during past 3 months).*
- *Disadvantages of being tested include: i) increased stress, anxiety, or depression upon learning of a positive result, ii) fear of discrimination.*
- *Washington State law requires that health care providers and laboratories report the name of anyone infected with HIV to the local health department, although names are not kept beyond 90 days after case report completion.*
- *If results are positive, partners need to be told that they have been exposed to HIV.*
- *Testing is voluntary, and the client may discontinue the testing process at any time.*

b) Give the client an opportunity to read the consent form and ask questions.
c) Assess for suicide/homicide risk; postpone test if client would harm themselves or others when receiving a "reactive" HIV test result.
d) Obtain agreement from client to permit venipuncture for confirmatory HIV testing, if rapid test results are "reactive."
e) Have client sign the Consent Form.
f) Provide FDA booklet and HIPAA handout.

Perform fingerstick blood draw, and initiate OraQuick Rapid Test

4) Provide Client-centered Prevention Counseling

a) Use open-ended questions to elicit information about risk behavior concerns.
b) Use clarifying and reflective questioning, as needed, to gain a complete understanding of client concerns and risk history.
c) Assess client's perception of HIV risk level. State objective assessment of HIV risk level. Express concern/support at an appropriate level.
d) Identify client's risk-reduction objective and negotiate a risk-reduction plan.
e) Problem solve issues concerning the plan.
f) Confirm with the client that the plan is reasonable and acceptable.
g) Assess client's support network and options.

5) Provide OraQuick Rapid HIV-1 Antibody Test Results

If Negative:

a) Reveal and identify test results clearly and simply for the client.

b) Review the meaning of the results.
- *Negative test results: the client has not been infected with HIV as of 3 months prior to testing.*
- *Test results are very accurate (at least 99.6%).*
- *The test screens for HIV antibodies (an immune system response to HIV infection), not the virus itself.*

c) State the need to consider the test result in the context of risk behavior during the past three months.

d) Make referral for follow-up HIV testing and other services, as appropriate.

e) Reinforce and build upon counseling messages to assist client to commit to a plan of action appropriate to his situation.

If Preliminary Reactive:

a) Reveal and identify test results clearly and simply for the client.

b) Review meaning of the results.
- *Positive results are preliminary and require confirmatory testing.*
- *The test screens for HIV antibodies (an immune system response to HIV infection), not the virus itself.*
- *In the context of a high risk client's risk history, positive results mean the client is likely to be infected; however, results are preliminary.*
- *Emphasize need for confirmatory testing in order to rule out chance of false positive result.*
- *Emphasize need to practice safe sex and needle use behavior to avoid transmitting the virus.*
- *Even when results are confirmed positive, the result does not indicate an AIDS diagnosis or a "death sentence."*
- *If results are confirmed positive, medical care is available to monitor health of immune system and limit harmful activity of HIV in the body.*

c) Counseling/support
- *Allow the client time to absorb the meaning of the test result.*
- *Explore client's understanding of preliminary result.*
- *Assess how client is coping with preliminary result.*
- *Identify and discuss the client's concerns. Answer client questions.*
- *Acknowledge the challenges of dealing with a preliminary, reactive result.*
- *Assess for risk of suicide and homicide given preliminary test results.*
- *Re-assess and discuss support options for coping with preliminary result.*
- *Assist client to establish a support plan for the next twenty-four hours.*
- *Assist client to establish a support plan for the time until confirmation test result appointment*

Collect Specimen for Confirmatory Test

d) Set up Appointment for Confirmatory Test Results Counseling Session
- *Stress the importance of returning for results.*
- *Gather client contacting information, if appropriate.*

e) Make referrals, as indicated.
- *Offer appropriate referrals for emotional support (e.g., Crisis Clinic) or medical care.*
- *If suicidal, actively refer for mental health evaluation.*

APPENDIX K:
PRELIMINARY REACTIVE COUNSELING MESSAGES

Feature of Rapid Testing	New Counseling Component/Message	When to Address the Issue
Test result is available at same visit - need to assess client's readiness to receive test result today	"In HIV rapid testing, the provider draws the sample (commonly through a finger-stick) and a screening test is performed. The results are available during your visit (include site specific info about when result will be available). If the result is non-reactive or negative, it means that you are not infected with HIV and no more testing is needed (unless you had a risk in the last 90 days). If the result is reactive, you may be infected and you will need a standard blood test or oral fluid test to tell for sure if you are infected. *How would you feel about getting your HIV test result during this visit? Do you have the support you would need if the results showed you might be HIV positive?"*	During pre-test counseling when discussing options for testing
Must assess patient's history of risk in order to help the patient understand the meaning of a preliminary positive test result	"Your rapid HIV test is reactive or preliminary positive. In a very small number of cases (4 per 1000) people who are actually HIV negative can have a rapid test that is reactive. As we discussed, the primary ways that people get HIV are through unprotected sex or sharing drug injection equipment with a person who has HIV. Understanding your risk factors for HIV will help me give you the clearest message about the results of your test. To do that I have to ask you some questions." Provider should proceed to review in-depth risk assessment questions.	Conduct in-depth risk assessment with client after providing a preliminary positive test result
Reactive or positive rapid test requires confirmatory testing	"Based on your risk factors (it is very likely) **or** (it is likely) **or** (there is a chance) that the preliminary test result is correct and that you have HIV. When a rapid test is preliminary positive a follow-up test is needed to tell us for sure whether you have HIV. We will arrange for that test to be performed before you leave and we should have the results in __ days. What are your questions?"	Provide interpretation of test result after conducting the in-depth risk assessment.

Persons who tests preliminary positive should receive counseling about avoiding spread to others	"Since your preliminary test shows that you might have HIV, it is important to take steps now to prevent spreading the virus to your sex or needle sharing partners. During our counseling session I explained how to reduce the risk of getting or giving HIV through sex or needle sharing. *What are your thoughts about being able to practice risk reduction with your partners?* (client responds) Let's work together to make a specific plan to address your concerns and special circumstances. I can offer assistance and even refer you to a provider where you can get ongoing support. It's very important to avoid exposing others to HIV and its important to protect yourself from any infections your partner might have so you can stay healthy. So, prevention is as important for you as it is for your partner."	After explaining the benefits of care and assessing client's support system
Important to ensure follow-up with persons who test preliminary positive	"Your appointment for getting your confirmatory test result is on ___ at ____. *How does that appointment work for you?* Let's double check your contact information...is this your correct address? phone number? Please feel free to contact me during the waiting period if you need to...if for any reason you can't make the appointment, give me a call and we can reschedule. This result is very important and I want to make sure I can help support you through this process. If it does turn out that you have HIV infection, we can work to get you to the care and treatment that can help you stay healthy."	At the end of the session

APPENDIX L: PREVENTION COUNSELING COMPONENTS
(Based on Project Respect)

1. Enhancement of Client's Self-Perception of Risk (2-3 minutes)
The counselor attempts to focus the client's attention on his/her behavior and the corresponding risk of acquiring HIV. The counselor's approach to this component of the session will shift based on the client's particular issues in addressing HIV risk:

- Enhance self-perception of risk;
- Address dissonance (examples when beliefs and behavior are at odds) and ambivalence (mixed feelings) about risk reduction;
- Increase self-efficacy (belief in one's power or ability to do something);
- Invoke peer and community norms.

The process is intended to help the client become motivated and invested in addressing HIV issues and concerns with the counselor. At the completion of this component of the session, the counselor's aim is to have the client fully engaged in the session and invested in reducing HIV/STD risk.

2. Explore the Specifics of Most Recent Risk Incident (2-3 minutes)
The counselor should have an open and inquisitive approach to this portion of the session. This approach will stimulate the client's curiosity and encourage him/her to self-reflect and examine his/her own behaviors. The exploration of the risk behavior should be specific. A thorough discussion of the most recent risk behavior may help the client clarify how the risk behavior occurred. What may have initially seemed like an accident or an unusual incident begins to have concrete circumstances that contributed to the client's decision to engage in high-risk behavior. This process can demystify the risk behavior for the client. The questions asked by the counselor are directed at eliciting the entire range of factors that may have contributed to the risk behavior. The counselor should be aware that emotions, recent life events, substance use, self-esteem, and other client characteristics and issues may influence a particular risk incident or pattern of risk behavior. The counselor and client should be working together to understand the context of the risk behavior. If the client's risk behavior is episodic or chronic, the counselor should attempt to discover the factors that contribute to this pattern of risk behavior.

3. Review Previous Risk Reduction Experiences (2-4 minutes)
The counselor should explore any changes initiated by the client to reduce his/her HIV risk(s). This provides the counselor with an essential opportunity to **support** and **reinforce** the client. The counselor should note all of the client's intentions, communications, and actions concerning HIV risk reduction. The counselor should elicit obstacles encountered by the client in considering or attempting behavior change. The counselor should gently and sensitively discuss the challenges the client has encountered or perceived. It is important to acknowledge that behavior change is a complex, difficult, and challenging process. It is helpful, particularly if the client has difficulty articulating his experiences with risk reduction, to explore his/her perception of community and peer norms concerning HIV prevention. Further, encouraging the client to articulate his/her attitudes and beliefs about HIV risk behavior may provide additional insight. This process allows the client to verbalize the extent to which he/she has addressed HIV issues and provides the counselor with insight into the client's strengths and difficulties in initiating and sustaining behavior change. During this portion of the session the counselor may educate and clarify misinformation for the client, as needed.

4. Synthesis of Risk Incident and Risk Pattern (2-4 minutes)
The purpose of this component of the session is to enable the client to gain an understanding of the complexity of factors that influence his/her risk behavior. The counselor summarizes the inter-related factors influencing the client's risk behavior. This summary provides the client with an organized perspective of his/her narrative. The counselor's approach to this should be empathic and non-judgmental, which will help the client understand his/her own behavior with compassion. This process enhances the counselor and client collaboration in reducing the client's risk of acquiring HIV. It may seem paradoxical, but the counselor must simultaneously convey a sense of urgency in understanding this behavior and be clear about the consequences should the client fail to prioritize and respond to this situation. This component of the session provides the foundation on which the risk reduction plan will be developed. The counselor will reference the highlights of this summary during test result and risk reduction component of the session.

5. Negotiate Risk Reduction Plan (4-5 minutes)
The risk reduction plan is a fundamental component of the prevention counseling session. The counselor should assist the client in identifying a behavior that corresponds to his/her risk and that he/she is invested in changing. It is essential that the plan match the client's skills and abilities with his/her motivation to change a specific behavior. The counselor should challenge the client to go beyond what he/she has previously attempted in terms of risk reduction. The plan must be specific in that it describes the who, what, where, when and how of the risk reduction process. It must be concrete in that it details the successive actions required of the client to implement and complete the risk reduction plan. Finally, it must be incremental in that it is directed at a single aspect of the risk behavior or one particular factor/issue that contributes to that risk behavior. The counselor should avoid supporting risk reduction plans that involve unreasonable or radical changes in the client's life. Global risk reduction messages such as "always wear condoms," "remain monogamous," or "abstain from sex" do not meet the criteria for an appropriate risk reduction plan. The counselor should ensure that the client agrees with the plan and is committed to its implementation. The client should be asked to critique the plan and identify problems with the plan. The counselor may even quiz the client on the plan or provide plausible examples of obstacles the client may encounter in initiating the plan. These obstacles should be problem-solved with the client and may require revising the plan. The process of developing a plan represents the client's movement toward risk reduction.

6) Identify Sources of Support and Provide Additional Referrals (3-4 minutes)
This component of the session is intended to identify or develop for the client peer and community support for HIV risk reduction, as well as to provide referral to professional services directed at addressing specific issues the client may have identified. The priority of this component of the session is to identify a specific friend or relative with whom the client will discuss his/her risk reduction plan and report to regarding the implementation and completion of the plan. This step is critical because in the rapid test scenario there is no second session for the counselor to review with the client his/her experience in implementing the plan. The process of the client checking in with someone about the plan is important because it gives enhanced meaning to the plan and increases the client's personal expectations about completing the plan. The client must trust this person and feel comfortable with his/her ability to keep the client's confidence. It is reasonable that the trusted person be the same person with whom the client is trying to initiate the behavior change plan. The counselor should discuss the process of confiding the risk reduction plan with a similar level of detail as that devoted to developing the plan. The counselor and client should establish a time frame during which this will occur. When will the client disclose the plan to this person? When will the client report the progress or completion of the plan to this person?

APPENDIX M: EXAMPLE CONSENT FORMS

As of July, 2003, Washington State law requires that providers conducting HIV tests obtain or ensure informed consent for HIV testing.

In addition, at this time Washington State law requires that providers conducting HIV test also provide clients with information about the test, test results, anonymous and confidential testing options, etc.

The purpose of the consent form is to twofold: 1) to provide the client with information about HIV and the HIV test; and 2) assure informed consent.

Providers can use this form as an HIV consent form as well as a basis for providing information to clients about the HIV test.

INFORMED CONSENT SAMPLE: ANONYMOUS TEST SITE

RAPID HIV ANTIBODY TEST CONSENT FORM

Please read this sheet carefully. This information will help you decide if you want an HIV test.

Introduction

The Human Immunodeficiency Virus (HIV) causes Acquired Immunodeficiency Syndrome (AIDS). People infected with HIV can infect others through unprotected sex, needle-sharing, and donating blood or other tissues. Mothers with HIV can infect their babies.

Rapid Testing for HIV

The rapid HIV antibody test is a finger-stick test. It's called a rapid test because your results will be available today.

This test detects antibodies to HIV, not the virus itself. Antibodies are the body's reaction to the virus. Because a body can take up to three months for antibodies to develop, results from the test will tell you whether or not you were infected 3 months ago.

The HIV antibody rapid test has two kinds of results: **Negative** and **Reactive.**

A **NEGATIVE** test result means that antibodies to HIV were not detected. This usually means that the person is not infected with the virus. However, if a person was infected recently (within the past 3 months) this infection may not show up on the test because it can take as long as 3 months for antibodies to develop. In such a case, a negative test result would not show the infection. Therefore, if a person has engaged in risky behavior within the three months before a negative test result, they should return for another test a full 3 months from the last time they put themselves at risk for HIV. This will make sure that they have the most accurate results. If a person with a negative test result has not engaged in risky behavior within the past 3 months, they can be confident they are uninfected with HIV.

REACTIVE results on this test are preliminary and must be confirmed with another test. If the results are reactive, blood must be drawn for a confirmatory test. Reactive results mean the test reacted and the person might have HIV. The person will not know for sure if they have HIV until they get the results from the confirmatory test. It can take up to two weeks for the results from the confirmatory test. It is very important for people to come back for the confirmatory test results to know if they have HIV or not. If a person has reactive results on the rapid test, it is important for them to take precautions to avoid transmitting the virus to others until they know for sure whether or not they are infected with HIV.

Benefits of Being Tested

For most people at risk for HIV, there are substantial benefits to being tested. Most importantly, people who find out they have HIV can get important medical care that can improve their prognosis. There are new medications available that may delay or prevent AIDS or other serious infections. Medication can help a women with HIV who is pregnant, or planning a pregnancy, to avoid passing the virus on to her baby. An HIV test result can help your health care provider give you the best health care.

There are other reasons to be tested. Many people find that knowing their test result helps them to take steps to protect their partners and themselves. Some people want to know their test result before beginning a new sexual relationship or becoming pregnant, or to better plan for the future. Many persons who are worried about HIV/AIDS will be reassured by learning that their tests are negative.

Testing for HIV is voluntary. At any time in the testing process you can choose to not be tested.

Risks and Disadvantages of Being Tested

Many people with positive test results experience stress, anxiety, and depression; in some cases, these feelings can be severe. Some persons with negative tests may be tempted to continue or increase unsafe behaviors, which would increase the risk of HIV infection. Many people are afraid that their test result will get into the wrong hands and that prejudice and discrimination might result. (See Privacy and Confidentiality, below.)

Privacy and Confidentiality

By law, HIV test results must be held in the strictest confidence. Your test result will not be released to any other person, agency, company, or government without your specific written permission, except as permitted by law.

Other Information

People who have a reactive result must return for the confirmatory test. This is an anonymous test site; therefore, we do not know how to find you. You must return to receive your results.

If your confirmatory HIV test is positive, your sexual and/or needle-sharing partner(s) must be informed that they have been exposed to the virus, that they may be infected, and that they should seek counseling and testing. Persons with positive tests can inform their partners themselves or we can help inform their partners for them. If positive persons are unable to inform their partner(s) or do not wish to do so, we can do it for them.

HIV is a Reportable Condition

HIV is reportable when someone tests positive through a confidential test (their real name was used and their medical records are kept with that name in the clinic), or when entering into treatment for HIV (again, their real name is used and medical records are kept with that name in the clinic). When a case of HIV is reported, the name is used only for the initial report. After 90 days, the name is converted and kept as a code. Because this is an anonymous test site, positive test results are not reported.

Consent

I have read and understand the above information. I was given an opportunity to ask questions, all of which have been answered to my satisfaction.

- I understand that this test requires a fingerstick; and if it is reactive, a confirmatory specimen will be collected by a venipuncture.
- I understand that if my results are negative, I am not infected with HIV (unless I put myself at risk in the past three months. In which case I will need to retest three months from my last exposure).
- I understand that if my results are reactive, I will need to have them confirmed with another test.
- I understand that I have an option to test anonymously here or confidentially at another site (and I have been told about these options) and I choose to test anonymously here.
- I understand that if I test positive for HIV with the confirmatory test, my partners must be notified of their exposure.
- I understand that if I test positive for HIV with the confirmatory test, because this is an anonymous clinic, I will not be reported as a case, but that I will be reported when I access health care.

☐ I authorize the (Your Agency's Name Here) to perform this test and to release the results to me.
☐ I refuse HIV testing today.

_____	_____	_____
Code of Person Testing	Code Name Signature	Date

_____	_____
When Applicable: Legal Guardian	Date

INFORMED CONSENT EXAMPLE: CONFIDENTIAL TEST SITE

RAPID HIV ANTIBODY TEST CONSENT FORM

Please read this sheet carefully. This information will help you decide if you want an HIV test.

Introduction

The Human Immunodeficiency Virus (HIV) causes Acquired Immunodeficiency Syndrome (AIDS). People infected with HIV can infect others through unprotected sex, needle-sharing, and donating blood or other tissues. Mothers with HIV can infect their babies.

Rapid Testing for HIV

The rapid HIV antibody test is a finger-stick test. It's called a rapid test because your results will be available today.

This test detects antibodies to HIV, not the virus itself. Antibodies are the body's reaction to the virus. Because a body can take up to three months for antibodies to develop, results from the test will tell you whether or not you were infected 3 months ago.

The HIV antibody rapid test has two kinds of results: **Negative** and **Reactive.**

A **NEGATIVE** test result means that antibodies to HIV were not detected. This usually means that the person is not infected with the virus. However, if a person was infected recently (within the past 3 months) this infection may not show up on the test because it can take as long as 3 months for antibodies to develop. In such a case, a negative test result would not show the infection. Therefore, if a person has engaged in risky behavior within the three months before a negative test result, they should return for another test a full 3 months from the last time they put themselves at risk for HIV. This will make sure that they have the most accurate results. If a person with a negative test result has not engaged in risky behavior within the past 3 months, they can be confident they are uninfected with HIV.

REACTIVE results on this test are preliminary and must be confirmed with another test. If the results are reactive, blood must be drawn for a confirmatory test. Reactive results mean the test reacted and the person might have HIV. The person will not know for sure if they have HIV until they get the results from the confirmatory test. It can take up to two weeks for the results from the confirmatory test. It is very important for people to come back for the confirmatory test results to know if they have HIV or not. If a person has reactive results on the rapid test, it is important for them to take precautions to avoid transmitting the virus to others until they know for sure whether or not they are infected with HIV.

Benefits of Being Tested

For most people at risk for HIV, there are substantial benefits to being tested. Most importantly, people who find out they have HIV can get important medical care that can improve their prognosis. There are new medications available that may delay or prevent AIDS or other serious infections. Medication can help a women with HIV who is pregnant, or planning a pregnancy, to avoid passing the virus on to her baby. An HIV test result can help your health care provider give you the best health care.

There are other reasons to be tested. Many people find that knowing their test result helps them to take steps to protect their partners and themselves. Some people want to know their test result before beginning a new sexual relationship or becoming pregnant, or to better plan for the future. Many persons who are worried about HIV/AIDS will be reassured by learning that their tests are negative.

Testing for HIV is voluntary. At any time in the testing process you can choose to not be tested.

Risks and Disadvantages of Being Tested

Many people with positive test results experience stress, anxiety, and depression; in some cases, these feelings can be severe. Some persons with negative tests may be tempted to continue or increase unsafe behaviors, which would increase the risk of HIV infection. Many people are afraid that their test result will get into the wrong hands and that prejudice and discrimination might result. (See Privacy and Confidentiality, below.)

Privacy and Confidentiality

By law, HIV test results must be held in the strictest confidence. Your test result will not be released to any other person, agency, company, or government without your specific written permission, except as permitted by law.

Other Information

People who have a reactive result must return for the confirmatory test results. If you do not return for your results, we will contact you to arrange for you to come in for your results.

If your confirmatory HIV test is positive, your sexual and/or needle-sharing partner(s) must be informed that they have been exposed to the virus, that they may be infected, and that they should seek counseling and testing. Persons with positive tests can inform their partners themselves or we can help inform their partners for them. If positive persons are unable to inform their partner(s) or do not wish to do so, we can do it for them.

HIV is a Reportable Condition

HIV is reportable when someone tests positive through a confidential test (their real name was used and their medical records are kept with that name in the clinic), or when entering into treatment for HIV (again, their real name is used and medical records are kept with that name in the clinic). When a case of HIV is reported, the name is used only for the initial report. After 90 days, the name is converted and kept as a code.

Consent

I have read and understand the above information. I was given an opportunity to ask questions, all of which have been answered to my satisfaction.

- I understand that this test requires a fingerstick; and if it is reactive, a confirmatory specimen will be collected by a venipuncture.
- I understand that if my results are negative, I am not infected with HIV (unless I put myself at risk in the past three months. In which case I will need to retest three months from my last exposure).
- I understand that if my results are reactive, I will need to have them confirmed with another test.
- I understand that I have an option to test confidentially here or anonymously at another site (and I have been told about these options) and I choose to be tested confidentially here.
- I understand that if I test positive for HIV with the confirmatory test, my partners must be notified of their exposure.
- I understand that HIV is reportable and if I test positive for HIV with the confirmatory test, my name will be reported as a case.

☐ I authorize the (Your Agency's Name Here) to perform this test and to release the results to me.
☐ I refuse HIV testing today.

_____
Print Name Person Testing

_____ _____
Signature Date

_____ _____
When Applicable: Legal Guardian Date

APPENDIX N: FREQUENTLY ASKED QUESTIONS

For more info: **http://www.cdc.gov/hiv/rapid_testing**

What is the OraQuick Rapid HIV-1 Antibody Test and how is it performed?

The OraQuick Rapid HIV-1 Antibody Test (OraQuick) is a screening test for HIV-1, the virus that causes AIDS. It is a single-use qualitative immunoassay that detects antibodies to HIV-1 in a fingerstick sample of blood. As with all HIV screening tests, a reactive test result needs to be confirmed by an additional, more specific test.

To perform the test, the fingertip is cleaned with alcohol and pricked with a lancet to get a small drop of blood. The blood is collected with a specimen loop and transferred to a vial, where it is mixed with a developing solution. The test device is then inserted into the vial. Results of the test can be read in as little as 20 minutes.

How well does the test work?

In the clinical studies by the manufacturer, OraQuick correctly identified 99.6% of people who were infected with HIV-1 (sensitivity) and 100% of people who were not infected with HIV-1 (specificity). FDA expects clinical laboratories to obtain similar results.

What are the limitations of the test? Does this test always give a correct result?

The limitations of this test are similar to the limitations of other HIV antibody tests, including:

- False Positives – although none were found in the clinical trial, a statistical analysis of the data indicates that a very small number of people who are not infected with HIV-1 will have reactive test results. As the test is used in broad outreach settings it is expected that false positives may be seen and therefore reactive results should not be considered definitive until confirmatory testing has been completed.
- False Negatives – a small number of people who are infected with HIV-1 will have negative test results.
- Delayed detection of exposure -- this test will not detect HIV-1 infection in people who were exposed within about three months prior to taking the test (since it can take that long for detectable antibodies to HIV-1 to appear in the blood).
- Follow-up testing – a reactive result is interpreted as preliminarily positive for HIV- 1 infection. Individuals with reactive test results should have follow-up testing using another method to confirm the initial test result.

For these reasons, all individuals taking this test must receive counseling both before being tested and after receiving their test results.

What type of counseling is done for rapid HIV tests?

Counseling for rapid HIV tests includes:

- Information about the importance of HIV testing
- Ways to reduce the risk of becoming infected with HIV
- Next steps for people who have a reactive test result
- Need for additional testing in people who have had a recent exposure to HIV

For more information about HIV counseling, see CDC's Divisions of HIV/AIDS Prevention website **(http://www.cdc.gov/hiv/dhap.htm).**

Does this test detect antibodies to HIV-2?

This test is approved to detect antibodies to HIV-1. Because HIV-2 is very rare in the United States, the CDC does not recommend routine screening for HIV-2 at this time.

Are blood donors allowed to be screened using the OraQuick test?
No. This test is approved to help diagnose HIV infection, not to screen blood donors.

Who is permitted to purchase and use the test?
Only clinical laboratories that meet certain quality assurance requirements may purchase OraQuick. In addition, only agents of clinical laboratories may use the test. An agent of the clinical laboratory is someone who works for the laboratory whether it is high complexity, moderate complexity, or waived. All customers will receive a letter indicating that through their purchase, they agree to meet these requirements.
Quality assurance requirements include:

- planned systematic activities to assure that requirements for quality will be met, and
- assurance that operators will receive and use the instructional materials.

What constitutes a "clinical laboratory?
A clinical laboratory is a facility for the examination of materials taken from the human body, to help diagnose, prevent, or treat a human disease or condition. CLIA requires all entities that perform even one test, including waived tests on ... "materials derived from the human body…" to meet certain Federal requirements. If an entity performs tests for these purposes, it is considered under CLIA to be a laboratory.

For CLIA's definition of a clinical laboratory, see 493.257 FR 7139, Section 493.2 Definitions.

What constitutes an "adequate quality assurance system?
An adequate quality assurance system consists of planned and systematic activities to ensure that a laboratory will meet certain requirements for quality. The CDC has developed quality assurance guidance. See:

http://www.cdc.gov/hiv/rapid_testing/materials/QA_Guidlines_OraQuick.pdf

OraQuick was originally approved as a moderate complexity test under CLIA. What is different now that the test is waived?
As a moderate complexity test, OraQuick could only be purchased and used by laboratories that were certified to conduct moderate complexity laboratory testing. Laboratories with this level of certification must meet CLIA requirements for personnel, training, and inspections, among others.

In contrast, laboratories performing only waived tests, must only meet the following requirements under CLIA:

- Enroll in the CLIA program;
- Pay a biennial fee to obtain a Certificate of Waiver; and
- Follow manufacturers' test instructions.

How can I obtain a Certificate of Waiver?
In Washington State, the Medical Test Site (MTS) program takes the place of CLIA. The MTA program is administered by the Department of Health, Office of Laboratory Quality Assurance (LQA). Information on obtaining a Certificate of Waiver can be found on the LQA website (www.doh.wa.gov/LQA.htm) or by calling (206) 361-2802.

How much does the test cost?
The manufacturer and the laboratory performing the test determine the fee for the test.

APPENDIX O: WAC 246-100-209

Counseling standards -- Human immunodeficiency virus (HIV) pretest counseling -- HIV post-test counseling. (1) Health care providers and other persons providing pretest counseling shall:

(a) Assess the individual's risk of acquiring and transmitting HIV by evaluating information about the individual's possible risk-behaviors;

(b) Provide at least one individual counseling session prior to HIV testing;

(c) Inform in writing or orally any individual planning to be tested for HIV that:

(i) Anonymous HIV testing is available through the local health department, home testing kits, or may be available through other community sources, and explain the differences between "anonymous HIV testing" and "confidential HIV testing"; and

(ii) If the test result is positive, sex and injection equipment-sharing partners, including spouses must be notified that they:

(A) May have been exposed to and infected with HIV; and

(B) Should seek HIV pretest counseling and consider HIV testing; and

(iii) The principal health care provider is required to refer identities of at-risk partners to the local health officer or authorized representative if:

(A) The HIV-infected individual either refuses or is unable to notify partners of exposure, possible infection, and need for pretest counseling and HIV testing; or

(B) The HIV-infected individual neither accepts assistance nor agrees to referral to the local health officer or an authorized representative for assistance in notifying partners; and

(iv) Unless HIV testing is anonymous, the principal health care provider is required to confidentially refer the identity of the individual testing positive to the local health officer or an authorized representative.

(2) When an individual is assessed by a counselor or health care provider as "virtually no risk of HIV infection," as defined in WAC 246-100-208 (3)(e)(v) a counselor or the health care provider shall, in addition to subsection (1)(a) of this section:

(a) Maintain a nonjudgmental environment during counseling which:

(i) Considers the individual's particular circumstances; and

(ii) Is culturally, socially, linguistically, and developmentally appropriate to the individual being counseled.

(b) Explain the nature, purpose, value, and reason for the HIV tests;

(c) In writing or orally, inform the individual to be tested that anonymous HIV testing is available through the local health department, home testing kits, or may be available through other community sources, and explain the differences between "anonymous HIV testing" and "confidential HIV testing;"

(d) Explain the possible effect of HIV testing and a positive HIV test result related to employment, insurance, housing, and other potential legal, social, and personal consequences;

(e) Develop and maintain a system of referral and make referrals that:

(i) Are accessible and confidential for those counseled;

(ii) Are acceptable to and supportive of those counseled;

(iii) Provide assistance to those counseled in maintaining risk reduction behaviors.

(f) Provide at least one individual counseling session at the time HIV test results are disclosed to individuals testing positive; and

(g) Maintain disclosure and confidentiality requirements in WAC 246-100-016.

(3) If the individual is assessed by a health care provider to be other than "virtually no risk of HIV infection," as defined in WAC 246-100-208 (3)(e)(v), the person providing pretest counseling shall maintain requirements in subsection (1) and (2) of this section and:

(a) Focus counseling on behaviors increasing the risk of HIV acquisition and transmission;

(b) Provide personalized risk reduction education to individuals who:

(i) Are men engaging in unprotected intercourse with other men at any time since 1977;

(ii) Used intravenous substances at any time since 1977, especially those sharing injection equipment;

(iii) Engaged in sex for money or drugs at any time since 1977;

(iv) Have had sexual and/or injection equipment-sharing contacts at any time since 1977 with persons listed in subsection (3)(b)(i), (ii), and (iii) of this section;

(v) Have been exposed to or diagnosed with a sexually transmitted disease;

(vi) Are at increased risk of HIV infection by definition of United States Public Health Services, Centers for Disease Control;

(vii) Are required by RCW 70.24.095 and 70.24.340 to receive HIV counseling and testing.

(c) Inform any individual planning to be tested for HIV of the need to notify sexual and injection equipment-sharing partners, including spouses, if test results are positive;

(d) Advise individuals listed in subsection (3)(b)(i), (ii), and (iii) of this section not to donate or sell blood, blood products, semen, organs, or other body tissues; and

(e) Emphasize or reemphasize the following counseling messages:

(i) The following will eliminate or decrease the risk of HIV infection:

(A) Sexual abstinence;

(B) A mutually monogamous relationship between uninfected people; and

(C) Following safer sex guidelines.

(ii) Do not share intravenous drugs and injection equipment;

(iii) Do not engage in behaviors in which blood, vaginal fluid, or semen is exchanged;

(iv) Condoms, even if used properly, do not supply absolute protection from HIV infection;

(v) Condoms may reduce risk of HIV infection if the condom is:

(A) Latex and used with a water-based lubricant rather than an oil-based lubricant, if a lubricant is used;

(B) Used in conjunction with spermicide during vaginal or anal intercourse; and

(C) Worn from start to finish of vaginal, oral, and anal intercourse.

(vi) Dental dams may reduce risk of HIV infection if the dental dam is:

(A) Latex; and

(B) Used from start to finish of oral intercourse.

(vii) The sexual behaviors having highest risk for HIV infection are those involving the exchange of blood or semen, especially receptive anal and vaginal intercourse;

(viii) Anal intercourse may increase the risk of condom failure and HIV infection;

(ix) Infected women should postpone pregnancy until more is known about how to prevent prenatal and perinatal transmission of HIV infection;

(x) Sexual negotiation skills can be learned to enhance risk reduction; and

(xi) Other sexually transmitted diseases, especially those causing genital ulcers, may increase the risk of acquiring or transmitting HIV infection.

(f) Make those counseled aware HIV retesting at a later date may be necessary or recommended.

(4) Persons providing post-test counseling shall:

(a) Follow requirements in subsection (1) of this section;

(b) Provide at least one individual counseling session at the time HIV test results are disclosed for individuals:

(i) Testing positive for HIV; or

(ii) Reporting practice of behaviors listed in (3)(b)(i), (ii), and (iii) of this section.

(c) If the individual being counseled tested positive for HIV infection:

(i) Unless testing was anonymous, remind the individual that the identity of the individual testing positive for HIV infection will be confidentially reported to the state or local health officer;

(ii) Provide assistance to persons in notifying partners, including spouses, and confirm those partners including spouses have been notified; and/or

(iii) Seek agreement to refer the name of the individual to the local health officer for assistance in notifying partners; and/or

(iv) Offer to refer partners for counseling and testing; and

(v) Develop or adopt a system to avoid documenting the names of referred partners in the permanent record of the individual being counseled; and

(vi) Offer referral for alcohol and drug and mental health counseling, including suicide prevention, if appropriate; and

(vii) Provide or refer for medical evaluation and antiretroviral treatment; and

(viii) Refer for tuberculosis screening.

[Statutory Authority: RCW 70.24.125 and 70.24.130. 99-17-077, § 246-100-209, filed 8/13/99, effective 9/1/99. Statutory Authority: RCW 70.24.022, [70.24].340 and Public Law 104-146. 97-15-099, § 246-100-209, filed 7/21/97, effective 7/21/97. Statutory Authority: RCW 43.20.050 and 70.24.130. 92-02-019 (Order 225B), § 246-100-209, filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 43.20.050. 91-02-051 (Order 124B), recodified as § 246-100-209, filed 12/27/90, effective 1/31/91. Statutory Authority: Chapter 70.24 RCW. 89-02-008 (Order 324), § 248-100-209, filed 12/27/88; 88-17-058 (Order 318), § 248-100-209, filed 8/17/88.]

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For persons with disabilities, this document is available on request in other formats. Please call 1-800-272-2437